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An essential step in home monitoring of pulmonary diseases: reliability of measurements with portable spirometry

Akciğer hastalıklarının evde izleminde önemli bir adım: taşınabilir spirometre ile yapılan ölçümlerin güvenilirliği

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Abstract

Purpose: Measurement of pulmonary function test (PFT) parameters is an essential component in diagnosing and monitoring pulmonary diseases. While traditional spirometers used in laboratories by trained technicians are the standard, they may face challenges including technical and accessibility issues. Portable spirometry might be a promising tool for remote monitoring. This study aims to evaluate the compatibility of data obtained by using a portable spirometer (MIR Spirobank®) versus traditional spirometry.

Materials and methods: Consecutive adult patients referred to the PFT laboratory from the outpatient clinic were included in this cross-sectional study. Each underwent PFT to obtain FVC, FEV1, FEV1/FVC, PEF, and FEF_{25-75} parameters. The intraclass correlation coefficient (ICC) was calculated, and Bland-Altman plots were created to evaluate the agreement of the measurements from the two devices.

Results: The mean age was 51.97±9.37 (33-72) years, and 56.7% of the 30 participants were male. Spirometry results indicated 56.7% normal, 33.3% obstructive, and 10% restrictive disorders using traditional methods, with compatible distributions observed for the portable spirometer (Kappa coefficient=0.656, p=0.0001). High agreement and correlation were found (p<0.0001), and the Bland-Altman plots showed good consistency between the devices.

Conclusion: Acceptable reliability may suggest the use of portable spirometry in telemedicine for assessing pulmonary diseases remotely and enhancing patient care.

Keywords: Portable spirometer, Spirobank, pulmonary diseases, remote monitoring, telemedicine.

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Öz

Amaç: Solunum fonksiyon testi (SFT) parametrelerinin ölçümü, akciğer hastalıklarının tanı ve takibinde temel bir bileşendir. Eğitimli teknisyenler tarafından laboratuvarlarda kullanılan geleneksel spirometreler standart olmasına rağmen teknik ve erişimle ilgili zorluklarla karşılaşılabilmektedir. Taşınabilir spirometreler, uzaktan izlem için umut verici bir araç olabilir. Bu çalışma, taşınabilir bir spirometre (MIR Spirobank®) ile geleneksel spirometre kullanılarak elde edilen verilerin uyumluluğunu değerlendirmeyi amaçlamaktadır.

Gereç ve yöntem: Kesitsel çalışmaya, göğüs hastalıkları polikliniğinden solunum fonksiyon testi laboratuvarına yönlendirilen ardışık erişkin hastalar dâhil edilmiştir. Her katılımcıya FVC, FEV1, FEV1/FVC, PEF ve FEF_{25-75} parametrelerini elde etmek için SFT uygulanmıştır. İki cihazdan elde edilen ölçümlerin uyumunu değerlendirmek için sınıf içi korelasyon katsayısı (ICC) hesaplanmış ve Bland-Altman grafikleri oluşturulmuştur.

Bulgular: Katılımcıların medyan yaşı 51,97±9,37 (33-72) yıl olup, 30 katılımcının %56,7'si erkekti. Geleneksel yöntemlerle yapılan spirometri sonuçları %56,7 normal, %33,3 obstrüktif ve %10 restriktif bozukluk göstermiş olup, taşınabilir spirometre ile uyumlu dağılımlar gözlenmiştir (Kappa katsayısı=0,656, p=0,0001). İki spirometre cihazı ile yapılan ölçümler arasında yüksek düzeyde uyum ve korelasyon tespit edilmiştir (p<0,0001), Bland-Altman grafikleri cihazlar arasında iyi bir tutarlılık göstermiştir.

Sonuç: Kabul edilebilir güvenilirlik ve geleneksel spirometri ile yüksek uyum, taşınabilir spirometrinin akciğer hastalıklarının uzaktan değerlendirilmesi ve hasta bakımını iyileştirmek için teletıpta kullanılabileceğini düşündürmektedir.

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Anahtar kelimeler: Taşınabilir spirometre, Spirobank, göğüs hastalıkları, uzaktan izlem, teletıp.

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Introduction

Chronic respiratory diseases pose a significant public health challenge worldwide. According to the World Health Organization (WHO), millions of people suffer from respiratory conditions, which are major causes of morbidity and mortality. Effective management of these diseases requires early diagnosis and continuous monitoring. Moreover, the growing burden of respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD) and asthma necessitates innovative approaches for early detection and ongoing management [1]. Portable spirometers offer a practical solution, enabling healthcare providers to monitor lung function remotely, thus ensuring timely medical interventions and reducing hospital admissions. Portable spirometers not only facilitate frequent monitoring but also empower patients to take an active role in managing their health conditions. Portable spirometers have reported potential to reduce healthcare costs through improved disease management and early intervention [2-6].

Measurement of basic pulmonary function test (PFT) parameters obtained through spirometry is an indispensable component in the diagnosis and monitoring of pulmonary diseases [7]. Traditional spirometry is performed in standardized laboratories, by trained technicians, using comprehensive equipment. Its non-invasive, safe, and low-cost nature, as well as its sensitivity in detecting restrictive and obstructive respiratory pathologies, make it one of the most frequently used initial diagnostic tests for evaluating respiratory complaints. However, studies indicate that the use of spirometry in chronic respiratory diseases is lower than expected and that delays in diagnosis occur. Furthermore, the heavy and expensive spirometry equipment, complex programs, maintenance fees, and lack of trained technicians affect the accessibility of traditional spirometry applications [8]. Additionally, the onset of the COVID-19 Pandemic led to the cessation of operations in PFT laboratories and changes in routine operations after the reopening of outpatient clinics. Measures to reduce patient visits to hospitals throughout the process have decreased spirometry use. Telemedicine, combined with portable diagnostic tools, can significantly reduce the burden on healthcare facilities and provide timely medical interventions [9-11]. Portable spirometers, with their compact size and ease of use, might be especially useful in resource-constrained situations and for patients with mobility concerns [12, 13]. Studies conducted with portable spirometers have shown that their results are compatible with traditional spirometry devices [2, 3, 14-17].

Despite the positive results reported from different countries, there is no data in our country (Türkiye) due to the low prevalence of both portable spirometers and remote patient assessment practices. In our clinic, patient-physician meetings have been continuing uninterruptedly for four years with the application of video conferencing-based telemedicine, which started with the closure during the pandemic period. The data from COVID patients and general pulmonary outpatient clinic patients has been analyzed and published [18, 19]. The results of the smoking cessation clinic have revealed noninferiority of telemedicine for e-cessation [20]. While taking detailed medical histories, performing general inspections, and monitoring clinical responses to treatment remotely with this method is possible, newly diagnosed patients need to come to the hospital for examination and testing [18]. It is known that tools like smart stethoscopes and portable spirometers can increase the effectiveness of telemedicine applications. Therefore, this study aims to evaluate the compatibility of spirometry data obtained in our unit with a portable spirometer (MIR Spirobank®) with the traditional spirometry data of the same patients.

Materials and methods

This cross-sectional pilot study included 30 consecutive adult patients who were referred to the PFT laboratory following the acquisition of a portable spirometer for our clinic and

the completion of training by the laboratory technician on the use of the device. The study was planned as a preliminary investigation to evaluate the agreement between the portable and conventional spirometers in clinical practice. Therefore, a sample size of 30 was considered sufficient for this initial assessment. This number is consistent with other pilot studies in the literature and aims to provide a foundation for future large-scale research [3, 21].

Study population

Between November 1 and November 30, 2023, adult patients presenting to the pulmonary clinic and referred to the PFT laboratory for spirometry were included after obtaining informed consent. In addition to conventional spirometry, measurements were taken with a portable spirometer. Adults who met any of the contraindications for spirometry listed in the American Thoracic Society (ATS) and European Respiratory Society (ERS) guidelines were excluded, including chest or abdominal pain of any cause, oral or facial pain exacerbated by a mouthpiece, stress incontinence, and cognitive impairment such as dementia or unconsciousness [22]. Additionally, adults who required more than eight maneuvers to meet reproducibility criteria were excluded.

Spirometry measurements

Each participant underwent pulmonary function testing using both the conventional spirometer and the portable spirometer. All measurements were performed under the supervision of the same PFT technician, and the order of testing was randomized. All maneuvers were performed in a seated position, with the participant wearing a nose clip and using a disposable mouthpiece. Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV_1), FEV_1/FVC ratio, Peak Expiratory Flow rate (PEF), and Forced Expiratory Flow between 25% and 75% of forced vital capacity (FEF_{25-75}) measured with the portable spirometer (Spirobank) were compared with the results of the traditional spirometry (Figure 1). The acceptability of the test was evaluated based on ATS/ERS criteria [22]. Patient demographics, including age, gender, height, and weight, as well as spirometry parameters, were recorded.

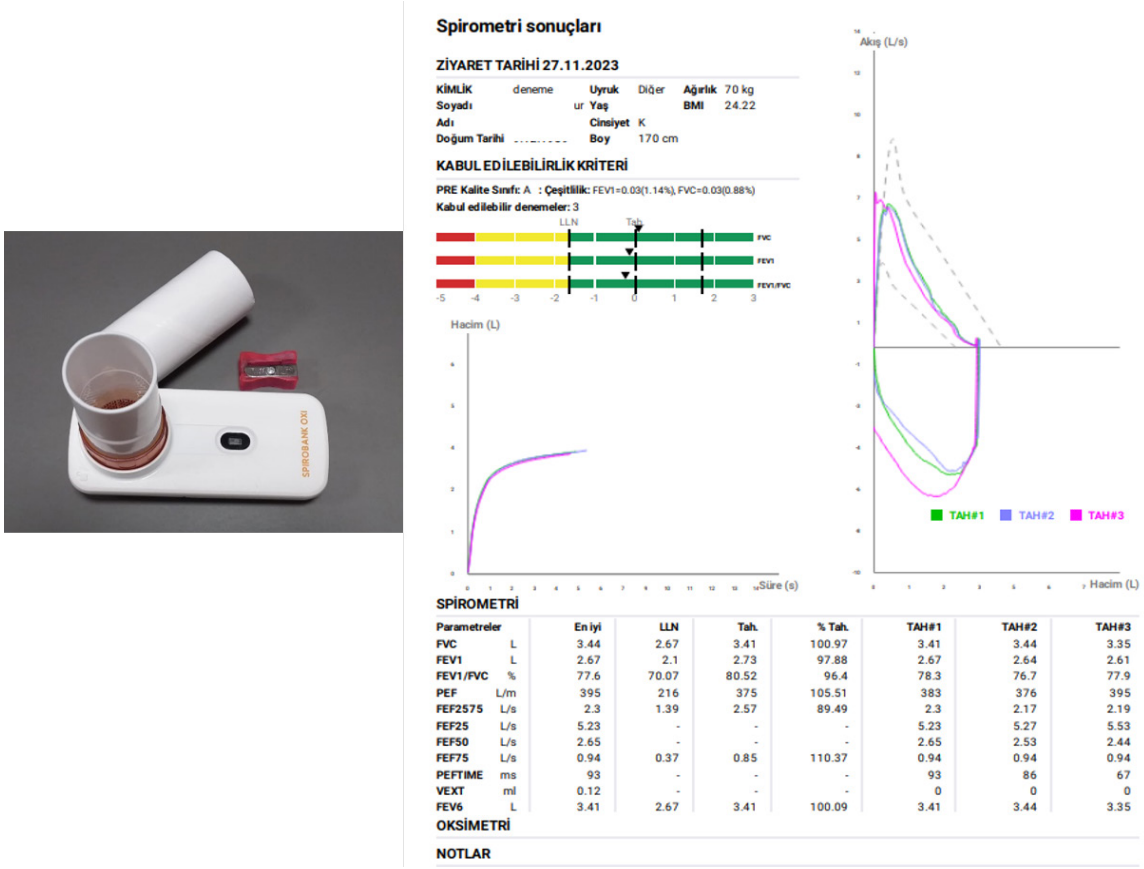

Figure 1. Portable spirometer (MIR Spirobank®) and a sample spirometry report

Statistical analysis

Data were analyzed using SPSS 25.0 software. Continuous variables were presented as mean±standard deviation (SD), and categorical variables were expressed as frequencies and percentages. The Intraclass Correlation Coefficient (ICC) was calculated to assess the consistency of the measurements obtained from the two devices. A Bland-Altman plot was generated to evaluate the agreement between the two devices.

This study was carried out in accordance with the Helsinki Declaration and was approved by the Pamukkale University Non-Interventional Clinical Research Ethics Committee (approval number: 17; date: 01.10.2024).

Results

In this retrospective, cross-sectional pilot study, spirometry measurements were performed on 30 participants referred from the pulmonary diseases outpatient clinic for PFT, using both traditional and portable spirometers. All participants met the inclusion criteria. The study cohort consisted of 56.7% males, with a mean age of 51.97±9.37 years (range: 33-72). Demographic and clinical characteristics of the participants, along with their spirometry parameters, are summarized in Table 1.

Table 1. Clinical characteristics and spirometry parameters of the participants

Clinical Characteristic		Mean±SD	Minimum-Maximum
Age, year		51.97±9.37	33-72
BMI, kg/m^2		30.4±4.6	22.67-39.06
Spirometry Parameters	**Device**	**Mean±SD**	**Minimum-Maximum**
FVC, L	Traditional	3.22±0.94	1.63-5.64
	Spirobank	3.23±0.94	1.67-5.62
FEV_1, L	Traditional	2.59±0.79	1.23-4.55
	Spirobank	2.54±0.78	1.32-4.67
FEV_1/FVC, %	Traditional	77.66±5.51	63.85-86.07
	Spirobank	77.69±5.32	64-84.5
PEF, L/s	Traditional	5.19±1.61	2.63-9
	Spirobank	3.44±1.07	1.72-5.59
FEF_{25-75}, L/s	Traditional	2.36±0.99	0.94-4.4
	Spirobank	2.47±1.02	0.99-5.15

BMI: body mass index; FVC: forced vital capacity; FEV_1: forced expiratory volume in one second; PEF: peak expiratory flow; FEF_{25-75}: forced expiratory flow between 25% and 75% of FVC has been exhaled

Interpretation of traditional spirometry results indicated that 56.7% of participants had normal lung function, 33.3% exhibited obstructive impairment, and 10% showed restrictive impairment. The portable spirometer (Spirobank®) yielded a consistent classification, demonstrating substantial agreement with traditional methods (Kappa coefficient=0.656, p=0.0001).

The Intraclass Correlation Coefficient (ICC) analysis revealed a strong correlation between the two devices, with all parameters showing statistically significant agreement (p=0.0001, Table 2). Notably, the ICC values for FVC, FEV_1, and FEF_{25-75} exceeded 0.92, underscoring their robust compatibility. Among these, FEV_1 and FVC exhibited the strongest correlations, while FEV_1/FVC and PEF showed slightly weaker, but still acceptable, correlations.

Table 2. The intraclass correlation coefficients (ICC) between spirometry values obtained with two spirometers

Spirometry Parameters	ICC (95% CI)	*p* value
FVC, L	0.984 (0.967-0.993)	<0.0001
FEV_1, L	0.959 (0.914-0.98)	<0.0001
FEV_1/FVC, %	0.547 (0.049-0.785)	<0.0001
PEF, L/s	0.749 (0.473-0.881)	<0.0001
FEF_{25-75}, L/s	0.941 (0.877-0.972)	<0.0001

FVC: forced vital capacity; FEV_1: forced expiratory volume in one second; PEF: peak expiratory flow; FEF_{25-75}: forced expiratory flow between 25% and 75% of FVC has been exhaled

To further evaluate the agreement between the devices, Bland-Altman plots were generated, illustrating the mean differences [bias] for each parameter alongside the 95% limits of agreement (LoA, ±1.96 (SD)). The plots demonstrated that the majority of the mean differences fell within the 95% LoA, affirming the interchangeability of the two devices for clinical use (Figure 2).

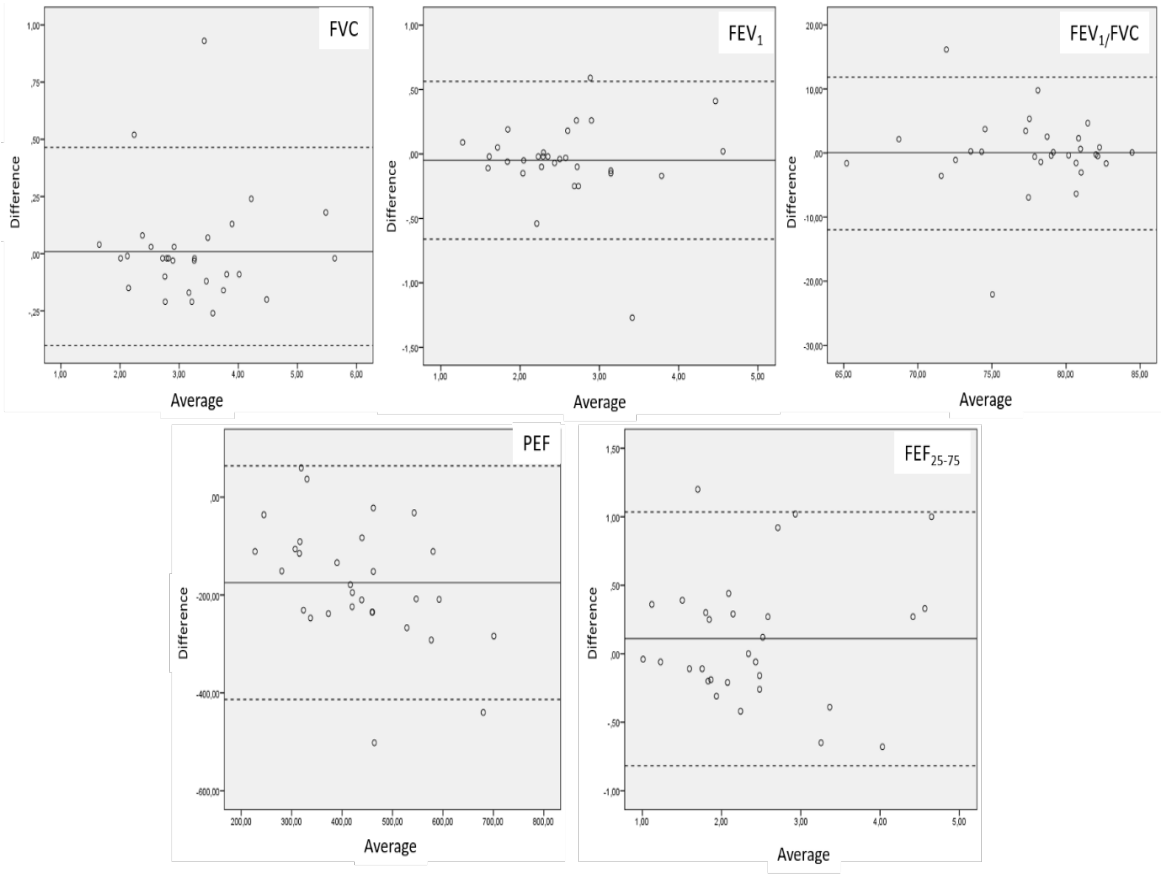

Figure 2. Bland–Altman plots for the evaluated spirometry parameters: FVC, FEV1, FEV1/FVC, PEF, FEF_{25-75}. Dashed lines represent the mean difference between measurements and dotted lines the 95% limits of agreement. FVC: Forced vital capacity; FEV1: Forced expiratory volume in one second; PEF: Peak expiratory flow; FEF_{25-75}: Forced expiratory flow between 25% and 75% of FVC has been exhaled

Discussion

This study indicates that the measurements obtained using the portable spirometer demonstrate high validity and reliability compared to traditional spirometry. There was strong agreement (ICC) and repeatability (Bland-Altman plots) between the two devices.

The high correlation observed in FEV_1 and FVC between the devices aligns with previous studies. While the ICC value for PEF was acceptable but relatively lower, this could be attributed to the dependence of PEF measurements on patient effort and the potential inconsistency in exertion across measurements, which is consistent with prior findings [14, 23-26]. However, a noteworthy difference from earlier studies was the slightly lower agreement observed in FEV_1/FVC compared to other parameters. FEV_1/FVC is a key parameter used to detect airway obstruction. In cases of severe airway obstruction, the prolonged expiration time due to early airway closure during forced expiration may lead to FVC maneuvers lasting 15-20 seconds, resulting in a lower FEV_1/FVC ratio than expected [27]. The relatively lower ICC for FEV_1/FVC in our study could be explained by one-third of the study population having obstructive airway disease and prolonged expiration times during repeated maneuvers. Nevertheless, the acceptable ICC values indicate that the portable spirometer provides reliable measurements.

Spirometry measurements are essential not only for diagnosing and monitoring chronic lung diseases but also for screening high-risk groups and conducting field studies. However, the use of traditional spirometry is limited in primary care due to challenges such as equipment portability and application difficulties [8]. In a community-based study conducted by Kumar et al. [28] in a rural area, portable spirometers were used to evaluate airway obstruction, revealing a high prevalence of COPD among the elderly population in rural settings. The elevated risk of respiratory diseases in this group, combined with their relatively limited access to healthcare, underscores the critical role of telemedicine and tools like portable spirometers in facilitating screening and early diagnosis. Integrating spirometry into primary care could help detect disease progression or exacerbations early, reducing hospital admissions and healthcare system burden. Portable spirometers may facilitate spirometry evaluations in primary care settings, enabling broader access for both patients and at-risk populations. Most previous studies on portable spirometers focused on patients with obstructive or restrictive lung diseases [17, 29]. The fact that approximately half of our study population had normal spirometry parameters highlights the potential of portable spirometers in broader applications.

While evaluating spirometry parameters is crucial, a comprehensive approach that includes a detailed medical history, systematic inquiry, thorough physical examination, and biopsychosocial evaluation remains essential. Tests like spirometry are integral but only one part of a holistic approach. Therefore, the effective and widespread use of portable spirometers depends on a platform enabling remote communication between patients and physicians. Telemedicine, although recognized for many years, gained prominence during the COVID-19 Pandemic and has become a routine part of healthcare systems in many parts of the world. However, in our country, telemedicine is still practiced in only a few centers, primarily outside public hospitals. In our clinic, a public university hospital, video-based telemedicine has been conducted uninterruptedly for nearly five years, evaluating a large number of patients and accumulating significant experience [18-20]. A study involving 478 patients evaluated via telemedicine in the pulmonary diseases outpatient clinic demonstrated that detailed medical histories could be obtained, previous test results could be reviewed, and inspection findings could be recorded through video consultation. It was also emphasized that instruments like smart stethoscopes and portable spirometers could significantly reduce hospital visits [18].

Remote monitoring could provide sustainable, high-quality healthcare services for patients living in remote areas, those with mobility limitations, or those under extraordinary circumstances such as pandemics or natural disasters. Additionally, it could alleviate the burden on hospitals. This pilot study represents the first step towards integrating portable spirometers into telemedicine. While Spirobank has undergone reliability studies in other countries, this is, to our knowledge, the first

such study conducted in Türkiye. Demonstrating that Spirobank measurements in the Turkish population are consistent and reproducible with traditional spirometry provides a solid basis for its integration into telemedicine practices.

Despite their advantages, portable spirometers have some challenges, such as device calibration, user training, and ensuring patient adherence to regular monitoring. However, calibration-free devices have been developed [29], and Spirobank is equipped with ultrasonic sensors resistant to daily variations in temperature and humidity [14]. Besides these concerns, a technical bias of our study might be considered as using the portable spirometer under the supervision of a PFT technician as well as the traditional spirometry to minimize measurement differences due to maneuver errors. Future studies assessing the compatibility and results of self-administered spirometry by patients after receiving training via different methods, especially in telemedicine settings, will be valuable.

This cross-sectional pilot study was designed to evaluate the reliability of Spirobank in a small population within the routine practice of a pulmonary diseases outpatient clinic where spirometry was requested. Although the sample size and diversity of respiratory diseases were limited, the study population included a heterogeneous group with obstructive or restrictive impairments as well as normal spirometry. Another limitation of the study was the absence of bronchodilator reversibility testing. Since the study focused on the reliability and validity of portable spirometry, it was limited to basic spirometry maneuvers. Larger studies incorporating bronchodilator reversibility testing, which is crucial for diagnosing and monitoring common airway diseases such as asthma and COPD, will provide more comprehensive insights.

In conclusion, in an era of expanding telemedicine and rapid technological advancements, portable spirometers are reliable devices that can enable remote patient assessment and monitoring. The findings of the recent study may pave the way for studying telemedicine methods in combination with portable spirometry, particularly to save time, money, and effort expended on follow-up visits, where appropriate.

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Author contributions: G.A. constructed the main idea and hypothesis of the study. N.C., G.A developed the theory and arranged/edited the material and method section. N.C., E.T., R.A.G, H.S. have done the evaluation of the data in the results section. The discussion section of the article was written by N.C, R.A.G. G.A. reviewed, corrected and approved. In addition, all authors discussed the entire study and approved the final version.

Conflict of interest: No conflict of interest was declared by the authors.

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