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The Reliability and Validity of a Portable Hand-held Spirometer for the Measurement of Various Lung Functions in Healthy Adults

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Objective: This study aims to assess the reliability and validity of the new hand-held spirometer as a potential substitute for traditional pulmonary function testing (PFT) devices.

Design: Cross-sectional study.

Methods: In this study, thirty healthy adults underwent spirometry using both the new hand-held spirometer and the MIR spirometer, which is a standard PFT device. Parameters including peak expiratory flow (PEF), forced expiratory volume in one second (FEV_1), and forced vital capacity (FVC) were measured and analyzed for validity and reliability. Inter-rater reliability and validity were evaluated through 95% limits of agreement (LOA) and intraclass correlation coefficients (ICC). Statistical analyses, including the Bland-Altman plots and the ICC, were utilized to assess agreement between the two devices.

Results: The new hand-held spirometer exhibited a good agreement with intra-class coefficient (ICC [2,1]) ranging 0.762 to 0.956 and 95% LOA of −1.94 to 1.80 when compared with MIR. The test-retest reliability of the hand-held spirometer analyzed using ICC [2,1] demonstrated a good level of consistency (ICC [2,1] =0.849-0.934).

Conclusions: In conclusion, the study aimed to assess the potential of the new hand-held spirometer as a viable alternative to traditional PFT devices, with a specific focus on its reliability and validity in spirometric measurements. The new hand-held spirometer exhibited good test-retest reliability across all measured variables, suggesting its potential as a valid and reliable tool for simultaneous PFT measurements.

Key Words: Portable spirometer, Pulmonary diseases, Hand-held spirometer, Respiratory function tests, Healthcare technology

Introduction

After social distancing, one of the measures taken against COVID-19, significant reductions in air pollution (ambient PM2.5, PM10, NO_2, and CO) have occurred in Korea. However, this reduction in air pollution is temporary and a regional example. Ambient air pollution continues to affect the Korean population and a large part of the global population. The World Health Organization (WHO) reports that approximately 4.2 million people worldwide die prematurely due to ambient air pollution. Population

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growth and industrialization are the cause of the highest air pollution levels, especially in Asian megacities [1].

Rapid industrialization stands as the primary driver of air pollution in the Republic of Korea. According to the Organization for Economic Cooperation and Development (OECD), the country exhibits the highest concentrations of air pollution and fine dust among OECD nations. As a result, the number of premature deaths is projected to increase from 359 per million in 2010 to 1,109 per million in 2060, the highest rate among OECD countries [2].

Respiratory diseases rank among the most prevalent non-communicable diseases globally [3]. Chronic obstructive pulmonary disease (COPD), characterized by airflow obstruction and respiratory complications, imposes a substantial burden of mortality and morbidity [4].

Asthma, characterized by airway inflammation leading to narrowed and swollen airways, poses significant challenges, including breathing difficulties, coughing, wheezing, and shortness of breath [5]. Chronic respiratory disease is not easy to detect due to the nature of the disease. The disease usually begins with weak symptoms and exacerbates slowly. The insidious onset and gradual exacerbation of chronic respiratory diseases make early detection challenging. However, early diagnosis shows great variation in disease progression and prognosis [6].

Respiratory muscle weakness significantly contributes to increased morbidity and mortality among stroke patients, adversely impacting respiratory function. Post-stroke weakened respiratory muscles, particularly the diaphragm and abdominal muscles, impede effective breathing and coughing mechanisms, leading to diminished vital capacity (VC), total lung capacity, maximum inspiratory pressure, and expiratory reserve volume [7].

Pulmonary function tests (PFTs) serve as vital noninvasive assessments to evaluate lung function in patients with respiratory disorders, providing insights into ventilation and gas exchange efficiency [8]. Key parameters derived from PFTs, including peak expiratory flow (PEF), forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC), play pivotal roles in screening respiratory diseases and assessing lung function. FEV_1 reflects the lung's ability to expel air forcefully in the first second after maximal inhalation, while FVC measures the total volume of air expelled during a maximal forced expiration. These parameters serve as fundamental indicators for respiratory health assessment [9]. PEF, representing the maximum expiratory flow per minute, is crucial for evaluating sputum discharge ability and expiratory function [10].

A PFT is routinely performed to assess respiratory function in people with pulmonary disorders. Patients need to apply to the hospital to perform these tests, and therefore it is especially difficult for them to constantly control themselves [11].

Rapid measurement methods are very important for patients with chronic diseases. Patients with chronic diseases such as diabetes and blood pressure can do their own personal care with portable personal healthcare devices such as glucometers and sphygmomanometers that can be used easily in daily life. However, patients suffering from chronic respiratory disease use only an analog-type peak flowmeter to measure PEF due to the lack of portable devices. This dearth of devices poses difficulties for users, requiring manual record-keeping and hindering practical access to results compared to other chronic illnesses [2].

The integration of smart technology, such as smartwatches and smartphones, into medical devices has revolutionized the portable medical device market, including spirometers. Advanced portable spirometers, capable of seamless connectivity with smartphone applications via Bluetooth, offer compactness, affordability, and enhanced usability. This integration facilitates remote monitoring and enables digital feedback on lung function, transforming portable spirometers into accessible personal care devices [12].

Current analog-type peak flow meters and spirometers are not equipped for real-time monitoring and are not of the appropriate size and cost-effective. Portable spirometry can facilitate remote monitoring by providing a cost-effective way to obtain pulmonary function measurements, and address these barriers by providing digital lung function feedback to patients and providers via a mobile app. Thus, the portable spirometer can be turned into a personal care device

that patients can use in daily life [13].

The scarcity of portable spirometers in Korea compared to other countries stems from their predominant use as training tools rather than for continuous lung function monitoring. On the other hand, most of the spirometers available in Korea are imported products, they have a higher price compared to the portable devices used for other chronic diseases. Therefore, it is difficult for the public to obtain them [14]. Spirometry is a useful tool for diagnosing respiratory diseases and monitoring patients with respiratory diseases. There is a greater need for domestic production for the widespread use of portable spirometers in Korea [15].

This study aims to assess the validity and reliability of the parameters obtained by comparing the developed new hand-held spirometer called the HooHoo spirometer with the MIR spirometer.

Methods

Thirty students aged between 20 and 30 living in Daejeon Metropolitan City participated in the study. The selection criteria were those with no history of chronic respiratory diseases such as asthma, chronic bronchitis, and pulmonary emphysema, and those with no history of chest wall surgery. Inclusion criteria encompassed individuals with no history of chronic respiratory conditions such as chronic bronchitis, asthma, or pulmonary emphysema, and those without a record of chest wall surgery. Exclusions were applied to individuals currently diagnosed with respiratory illnesses undergoing treatment, experiencing symptoms such as dizziness or chest pain during the intervention, or failing to provide written informed consent. Approval for the study was obtained from the Konyang University Institutional Review Board (IRB) (Approval number: KYU 2021-11-007-002).

The sample size was determined based on previous studies investigating the reliability and validity of portable spirometry devices [2, 13]. Based on calculations using G*power 3.1.9.4 software, with a significance level (α) of .05, a power level of 0.80, and a correlation coefficient (r) of 0.5, the appropriate number of subjects required was determined to be 29. The number of required subjects has been set to 30 to account for potential attrition.

Participants were selected through a recruitment notice posted on a social recruitment platform. A copy of the explanation of the "Informed Consent Form" was provided to each participant who voluntarily participated through the recruitment notice. After the researcher detailed the study's purpose, experimental procedures, and methods orally, the experiment was conducted on participants who provided written informed consent. This study was completed in a single visit, with the total participation time for each participant being approximately 50 minutes. All experiments and measurements were conducted by a clinical pathologist, ensuring the accuracy and reliability of the procedures.

All participants performed spirometry with both a handheld MIR spirometer (MIR, Italy) and the new hand-held spirometer (HooHoo, AICON Ltd., Korea) to verify the validity of the HooHoo spirometer. The MIR Spirometer, compliant with the guidelines set forth by the American Thoracic Society (ATS), measures PEF, FVC, and FEV_1 in real time via Bluetooth connectivity with a smartphone or tablet [16]. The HooHoo spirometer is a new handheld PFT device that measures the volume of air entering and exiting the user's lungs through a mouthpiece. The HooHoo spirometer is largely composed of a flow head, main body, nose clip, mouthpiece filter syringe, and power cord. This device is a portable spirometer (143×34.8×51mm, 106g) that can measure lung capacity through an infrared sensor to convert the speed of respiratory vortex flow, generated by the user exhaling or inhaling as rapidly and forcefully as possible, into a quantifiable value. This data is then transmitted via Bluetooth communication to a mobile application, which measures and displays the volume and flow rate of air passing through the user's lungs.

The HooHoo spirometer and the MIR spirometer each recorded at least three valid data measurements. A three to five-minute break was allowed within each measuring device, and a ten-minute break was taken between the two devices. The order of measurement with each device was randomly assigned. A trained technologist standardized all measurements following current ATS/ERS guidelines. The PEF, FEV_1, and

FVC values obtained from each spirometer were digitally recorded for later statistical analysis.

Statistical analysis

The data's normality was assessed using the Shapiro-Wilk test, which is suitable for small sample sizes. All spirometric parameters (PEF, FEV_1, FVC) were tested for normal distribution. The Shapiro-Wilk test results indicated that the data for all parameters were normally distributed ($p > 0.05$), justifying the use of parametric tests for subsequent analyses. The mean and standard deviation (SD) of results obtained from each spirometer (the MIR and HooHoo) were calculated. The repeatability and accuracy of spirometric data were statistically compared between the two devices using the Bland–Altman method, which is ideal for assessing agreement between medical instruments measuring continuous variables [17]. Paired t-tests were also conducted to examine bias in mean differences for spirometric parameters recorded by each device. Intraclass correlation coefficient (ICC) analysis evaluated reproducibility and correlation between results obtained from the HooHoo and MIR spirometers, with ICC values indicating the degree of similarity between values [18]. Values less than 0.750 were considered medium or low (moderate), 0.750 to 0.900 as good, and over 0.900 as excellent [2]. Statistical analyses were performed using Microsoft Excel 2018 (Microsoft, Redmond, WA, USA) and IBM SPSS Statistics, version 25, with p-values < 0.05 considered statistically significant. Bland-Altman plots were generated using Medicalc ver. 19.3.1 (Medicalc software, Ostend, Belgium) to visualize bias in mean differences between values obtained from the two spirometric devices.

Table 1. General characteristics

Variable	Value
Age (years)	21.67 ± 2.88
Gender (male/female)	18 / 12
Weight (kg)	67.93 ± 13.51
Height (cm)	168.67 ± 6.99

Results

The study comprised thirty participants, including 18 men and 12 women, with a mean age of 21.67 years, a mean height of 168.67 cm, and a mean weight of 67.93 kg <Table 1>. Each participant underwent spirometry testing with the MIR and the HooHoo spirometers, recording parameters such as FEV_1, FVC, and PEF.

Comparison of spirometric measurements between the HooHoo and MIR spirometers using paired t-tests revealed no significant differences in FEV_1 and PEF. However, there was a significant difference in FVC measurement results measured through the HooHoo and the MIR spirometers <Table 2>.

We employed ICC and correlation plots to assess the agreement and correlation between the two devices. An excellent correlation coefficient (ICC) of 0.907 (95% confidence interval [CI], 0.804-0.956) was observed for FVC, while FEV_1 and PEF demonstrated good ICC values of 0.888 (95% CI: 0.764-0.947) and 0.887 (95% CI: 0.762-0.946), respectively. To visualize the mean difference or bias and the 95% limits of agreement (95%LoA, ±1.96 SD) between the devices for each measured value, we utilized Bland-Altman plots. The 95% LOA were as follows: for FVC, −0.64 to 1.21; for FEV_1, −0.94 to 1.21; and for PEF, −0.70 to 1.80. Inspection of these plots indicates that the majority of mean differences fall within the 95% LOA <Table 2><Figure 1>.

The test-retest measurements conducted with the HooHoo were analyzed using paired t-tests, revealing no significant difference in the measurement results <Table 3>. The correlation coefficient was excellent for ICC (2, 1) of FVC (coefficient, 0.934; 95% confidence interval [CI], 0.861-0.969). However, the ICC of FEV_1 (coefficient, 0.846; 95% CI, 0.683-0.928) and PEF (coefficient, 0.856; 95% CI, 0.698-0.932) was good. The 95% LOA were as follows: for FVC, −0.79 to 0.72; for FEV_1, −1.17 to 1.36; and for PEF, −1.8 to 2.1. Examination of the Bland-Altman plots reveals that the majority of mean differences fall within the 95% LOA <Table 3><Figure 2>.

Discussion

Table 2. Mean differences: FEV_1, FVC, and PEF values of MIR and HooHoo

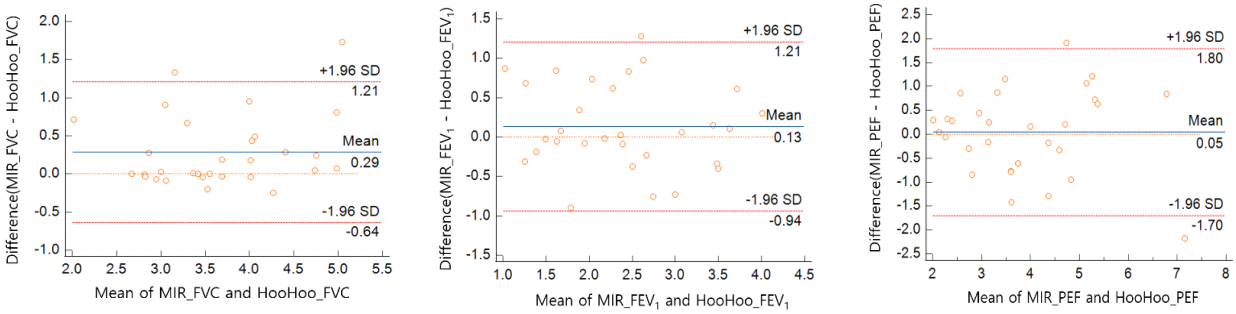
Variables	HooHoo (n=30)	MIR (n=30)	Difference	t (*p*)	ICC [2,1] (95% CI)	95% LOA (min, max)
FVC (L)	3.51±0.77	3.80±0.85	0.29±0.47	3.330(0.002)	0.907(0.804-0.956)	−0.64, −1.21
FEV_1 (L)	2.32±0.89	2.45±0.84	0.13±0.55	1.343(0.190)	0.888(0.764-0.947)	−0.94, −1.21
PEF (L/min)	3.86±0.42	3.91±1.38	0.05±0.89	0.293(0.772)	0.887(0.762-0.946)	−1.70, −1.80

Values are presented as mean ± SD. FEV1 forced expiratory volume in the first second, FVC; forced vital capacity, PEF; peak expiratory flow, ICC; intraclass correlation coefficient, CI; confidence interval, 95% LOA; 95% limits of agreements

Table 3. Test-retest reliability of the HooHoo variables for the two measurement sessions in participants.

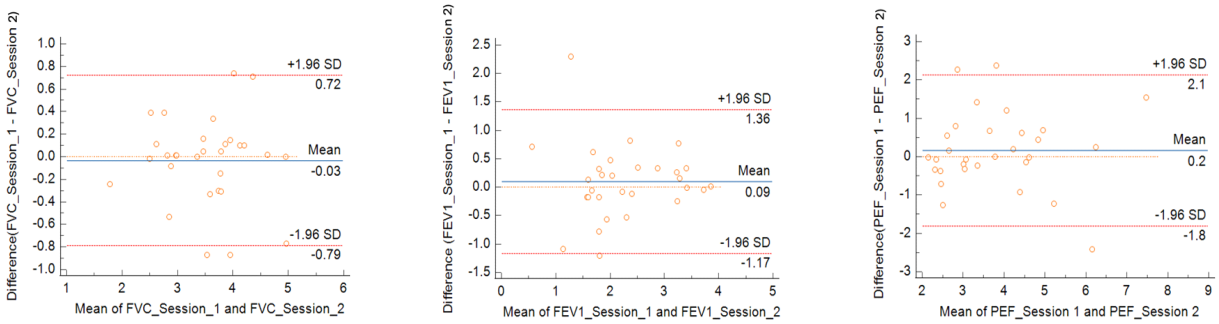
Variable	Session 1	Session 2	Difference	t (p)	ICC [2,1] (95% CI)	95% LOA (min, max)
FVC (L)	3.51 ± 0.77	3.55 ± 0.78	−0.03 ± 0.39	−0.483(0.632)	0.934(0.861-0.969)	−0.79, −0.72
FEV_1 (L)	2.32 ± 0.89	2.23 ± 0.89	0.09 ± 0.65	0.785(0.439)	0.849(0.683-0.928)	−1.17, −1.36
PEF (L/min)	3.86 ±1.42	3.69 ± 1.41	0.16 ± 1.00	0.890(0.381)	0.856(0.698-0.932)	−1.8, −2.1

Values are presented as mean ± SD.
FEV_1 forced expiratory volume in the first second, FVC; forced vital capacity, PEF; peak expiratory flow, ICC; intraclass correlation coefficient, CI; confidence interval, 95% LOA; 95% limits of agreements



(a) FVC (b) FEV_1 (C) PEF

Figure 1. Bland-Altman plot between the HooHoo and the MIR for pulmonary function test variables in participants (FEV_1 forced expiratory volume in the first second, FVC; forced vital capacity, PEF; peak expiratory flow).



(a) FVC (b) FEV_1 (C) PEF

Figure 2. Bland-altman plot for the pulmonary function test variables between session 1 and session 2 of the HooHoo in participants (FEV_1 forced expiratory volume in the first second, FVC; forced vital capacity, PEF; peak expiratory flow).

This study focused on investigating the concurrent validity and reliability of the HooHoo spirometer in conjunction with thirty young adults in their twenties. Clinical trials utilizing the MIR spirometer, a standard PFT device, were conducted to collect comparative data. The analysis aimed to evaluate the agreement between the HooHoo and MIR spirometers.

The ICC values between the parameters obtained from the two devices demonstrated great reliability, with certain key parameters (such as FEV_1, FVC, FEV_1/FVC) exhibiting ICC values exceeding 0.887. Although ICC values for FEV_1 and PEF were slightly lower but still significant (ICC > 0.75), which was consistent with previous studies [19, 20]. The 95% LOA provided reference data indicating symmetrical results for each variable, with most results demonstrating symmetry. In this study, the values for each variable were FVC −0.64 to 1.21, FEV_1 −0.94 to 1.21, and PEF −1.71 to 1.809. The test-retest reliability analysis of the HooHoo spirometer showed great reliability (0.849 < ICCs < 0.934) for all variables, with 95% LOA values symmetrically distributed within a narrow range.

The paired t-test results indicated no significant differences in FEV_1 and PEF measurements between the HooHoo and MIR spirometers. However, a significant difference was found in FVC measurements. This suggests that, for most parameters, the HooHoo spirometer provides comparable results to the MIR spirometer. The ICC values demonstrated strong reliability for all parameters (ICC > 0.75), indicating a high level of agreement between the two devices. The strong ICC values indicate that both devices reliably measure the same constructs, despite minor variations that are not statistically significant according to the t-test. This discrepancy underscores the robustness of the HooHoo spirometer, affirming its potential as a reliable tool for respiratory monitoring.

The indicators derived from the PFTs test play a pivotal role in evaluating respiratory health status. Regular monitoring of respiratory health is crucial, particularly for individuals with chronic respiratory conditions [21, 22]. However, accessing specialized medical facilities equipped with PFT devices poses a significant challenge. The HooHoo spirometer, utilizing sensors and innovative IT technology, aims to overcome accessibility and usability limitations associated with existing PFT devices.

Based on the aforementioned results, this study was able to elucidate the high agreement rate observed between the test-retest sessions. This study ensured robust control over lung function variables by conducting examination and test-retest sessions simultaneously, a measure aimed at minimizing potential temporal fluctuations. This approach was implemented while maintaining the measurement posture of each participant according to the American Thoracic Society (ATS) standard [21, 22, 23, 24]. Additionally, the testing environment was meticulously managed to minimize spatial variability, with both primary and secondary tests conducted in identical conditions of space and temperature. These rigorous controls collectively contributed to the high level of agreement observed between test-retest sessions, bolstering the reliability and validity of the study's findings.

Spirometry is significant as both a therapeutic and diagnostic tool within primary care settings; however, its utilization remains limited [25]. The HooHoo spirometer is a new handheld PFT device that can measure lung capacity through respiratory sensing, and train respiratory patients by measuring inhalation pressure and expiratory pressure. Its portability, reduced instrument cost, smaller size, and ease of calibration checks enhance its applicability in various healthcare settings.

Kim et al [2] recorded the reliability of the Spirokit device, which has similar features to the HooHoo spirometer used in this study. According to the study conducted by Kim et al, all PFT values of Spirokit (FVC, FEV_1, and PEF) showed a very high level of reliability as 0.999, 0.997, and 0.988, respectively. The HooHoo spirometer in our study showed high reliability in FVC, FEV_1, and PEF values of 0.934, 0.849, and 0.856, similar to Spirokit. Additionally, Kim et al compared the reliability of the Spirokit device with another similar device and recorded a very high concordance rate of FVC, FEV_1, and PEF values of 0.999, 0.997, and 0.988, respectively.

This is similar to the high concordance rate between the HooHoo and MIR spirometer. In another study, Xiao et al [12] compared the concordance of two

devices and noted that all PFT values were between $0.774 < ICC < 0.951$. Although ICC values in this range show a high agreement rate, there are differences between PFT values, and FVC and PEF values are lower than other PFT values. In our study, although the PFT values obtained from both devices showed a high concordance rate with ICC values exceeding 0.887, the ICC values for FEV_1 and PEF were lower than other PFT values. These two studies are similar in that there is a difference between the ICC values for PFT. However, this difference is not large enough to affect the reliability of the devices.

The results of this study not only confirm the statistical robustness and reliability of the HooHoo spirometer compared to the MIR spirometer but also highlight significant clinical implications. The introduction of portable spirometers like the HooHoo could revolutionize the management and monitoring of chronic respiratory diseases, particularly in settings with limited access to traditional diagnostic tools. By providing a compact, cost-effective, and user-friendly alternative to conventional PFT devices, the HooHoo spirometer can facilitate regular lung function monitoring at home. This can lead to earlier detection of respiratory issues, timely interventions, and better overall management of conditions such as COPD and asthma [2, 8]. Moreover, in rural or underserved regions where healthcare resources are scarce, portable spirometers can bridge the gap in respiratory care, allowing patients to monitor their lung health without frequent visits to medical facilities [16]. This integration into routine healthcare practices could enhance patient compliance, reduce hospital admissions, and ultimately improve the quality of life for individuals with chronic respiratory conditions [16, 19].

This study has several limitations. First, this study solely involved healthy participants in their twenties, limiting the generalizability of the conclusion. Second, the inability to include patients with respiratory diseases restricts the applicability of the findings to this population. As a result, the ability of this study to evaluate the reliability and validity of the spirometer in patients with respiratory diseases was somewhat limited.

Taken together, additional studies should be conducted to address these limitations through comprehensive research involving diverse participant demographics, including patients with respiratory diseases, in order to prove the reliability and validity of the HooHoo spirometer.

Conclusion

In conclusion, the study aimed to evaluate the HooHoo as a potential substitute for conventional PFT devices, focusing on its validity and reliability in spirometric measurements. The findings demonstrated good agreement and reproducibility between the HooHoo and the established MIR spirometer, particularly among young adults of both genders.

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