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Research Article

ACCURACY OF A HANDHELD SPIROMETER IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE SCREENING OF PATIENTS' COMPANIONS AT THE HASSAN II UNIVERSITY HOSPITAL IN FES, MOROCCO

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A B S T R A C T

Respiratory screening is an important step in identifying respiratory problems. It is important to note that early screening can help prevent the disease from worsening and improve quality of life. The aim of this study was to explore the capacity of a new portable spirometer compared with standard spirometry in screening for chronic obstructive pulmonary disease. A cross sectional study was conducted among patients' companions consulting in the pulmonology department of the HASSAN II University Hospital of Fez. The participantsbenefited from two spirometry tests: one performed by a reference spirometer, and the other by a new connected spirometer.We included 222 participants, 63.1% of whom were female, with an average age of 52.2±10.4. Data showed a strong correlation between absolute values of FEV1, FVC and FEV1/FVC ratio measured with the Smart Air mobile spirometer and conventional office spirometry, with r=0.87,r=0.84 and r=0.75, respectively. The connected spirometer Air-Smart detected 88 (39.6%) participants with obstructive ventilatory disorder (OVD). The Kappa coefficient between the two devices was k=0.61 (95% CI (0.55; 0.67)). The Air Smart could be an exciting and affordable tool for screening purposes in the primary care setting.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a major public health issue worldwide. According to the WHO, chronic obstructive pulmonary disease (COPD) is the third leading cause of death worldwide. It caused 3.23 million deaths in 2019. Almost 90% of COPD deaths in people under 70 occur in low- and middle-income countries.Smoking accounts for over 70% of COPD cases in high-income countries. In low- and middle-income countries, it accounts for 30 to 40% of COPD cases, and indoor air pollution is a major risk factor. (Anon s. d.2023-a)

According to the Burden of Obstructive Lung Disease study, the average prevalence of chronic airway obstruction in Morocco was 11.2% in men and 8.6% in women. This prevalence remains largely underestimated, and specialists estimate that 5-10% of people over the age of 40, both men and women, are affected by the disease, with most cases going undiagnosed.(Anon 2022)The average risk attributable to smoking in the population was 5.1% in men and 2.2% in women.(Burney *et al*. 2021)

Thus, early detection of COPD is important to prevent further deterioration in lung function through pharmacological intervention and more targeted smoking cessation measures.(Calverley *et al*. 2007),(Decramer *et al*. 2009)

The typical screening process entails utilizing a spirometer and seeking consultation from a specialized doctor. This method may pose limitations for the patient, as it involves potential appointment delays and an imperative requirement for specialist care. Consequently, this can result in a diagnostic delay and a decline in the patient's respiratory capabilities.

In recent years, portable spirometers have been made available by various manufacturers, enabling assessment of air volume and flow in the lungs, which can reveal respiratory abnormalities associated with COPD. They are inexpensive, ultra-portable and easy to use. As such, these devices could be used as a case-finding tool for COPD. The portable spirometer has good sensitivity and specificity for identifying airflow limitation compared with standard laboratory spirometry. (Vandevoorde *et al*. 2005),(Du Plessis *et al*. 2019a),(Fujita *et al*. 2020) .

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Mini-spirometryisoftenused in doctors' surgeries, pharmacies or screening clinics to perform a rapid, non-invasive test of lungfunction. It can be performed by blowing into a small, portable device that records the measurements.(Masson s. d.)Hence, Mini-spirometry could be an appropriate tool for early detection of COPD and therefore initiating appropriate treatment and preventing disease progression.

However, it is important to note that mini-spirometry provides only a preliminary assessment of lung function. If the results indicate possible obstruction, full spirometry is generally recommended to confirm the diagnosis of COPD and assess the severity of the disease.(Ching *et al*. 2014)

The aim of this study is to explore the capacity of a new portable spirometer (SMART-AIR) compared with standard spirometry in screening for COPD in patients' companions at the Hassan II University Hospital in Fez, Morocco.

MATERIALS AND METHODS

Design

This is a cross sectional study conducted in the Pneumology Department of the Hassan II Hospital in Fez, from May 2021 to June 2022.

Subjects

The sample was selected among patient's companions, consultants in the pulmonology department at the Hassan II university hospital in Fez.

Inclusion criteria

The study included participants aged over 40 who provided written informed consent.

Exclusion criteria

Patients with any of the contraindications to spirometry listed in the guidelines of the Spanish Society of Pneumology and Thoracic Surgery (SEPAR) were excluded: recent hemoptysis of unknown origin, recent pneumothorax, active respiratory infections, recent or unstable myocardial infarction, aneurysm (cerebral, thoracic, abdominal).(García-Río *et al*. 2013)

Data collection

The primary questionnaire utilized in this project was constructed predominantly by adapting validated pre-existing questionnaires employed in multinational surveys. Key sections of the questionnaire were drawn from the HAS (High Health Authority) Questionnaire, adapted from the Global Initiative for Chronic Obstructive Lung Disease, 2014 (Anon s. d.2023-b). This comprehensive questionnaire covers various aspects, including demographic information (age, gender, weight, height, BMI), functional indicators (cough, sputum, dyspnea), comorbidities (such as heart disease, diabetes, and others), smoking habits, occupational exposures, and pneumological history.

All participants underwent spirometry using both a conventional "Easy-one" office spirometer and the "Smart Air" study spirometer. Trained personnel, including a pulmonology resident and a spirometry technician, conducted measurements in a standardized manner. The process was repeated until obtaining a high-quality, reproducible measurement.

Features

Smart-Air is a Class IIa CE-certified medical device in compliance with ISO 27782 and 23747(Ramos Hernández *et al*. 2018). Because of the accompanying "Air MD" application, the following indices are recorded after spirometry: forced expiratory volume in 1 second (FEV1), forced vital capacity (FVC), FEV1/FVC ratio, peak expiratory flow (PEF), duration of spirometry. In addition, the flow-volume loop is also presented, which is valuable for diagnostic purposes.

The device features a turbine mechanism to take measurements inside disposable nozzles. It does not require calibration, but age, sex and height parameters are entered prior to spirometry. To perform spirometry, the participant is asked to exhale air into the turbine. This air turns a motor, and the device records the rotor speed and in turn transfers the data to the smartphone app. When the patient initiates exhalation, a stopwatch lights up and changes color from red to green after 6 seconds of exhalation.

Spirometric diagnosis of obstruction

A diagnosis of an obstructive pattern was established when the FEV1/FVC ratio was less than 70%. Subsequently, the obstruction was categorized into subgroups based on the severity of airway obstruction, aligning with the guidelines provided by the Global Initiative for Chronic Obstructive Lung Disease (GOLD)(Vestbo *et al*. 2013): stage 1 if FEV1 was ≥80% predicted, stage 2 for 50% ≤FEV1 <80% predicted, stage 3 for 30% ≤FEV1 <50% predicted, and stage 4 if FEV1 was <30% predicted.

Statistical analysis

Data entry was performed using Excel 2013 and analysis was performed using SPSS version 26 at the epidemiology laboratory of the Faculty of Medicine and Pharmacy of Fez, Sidi Mohamed Ben Abdellah University. In the first stage, a descriptive statistical analysis was carried out. Qualitative variables were described as percentages, and quantitative data as mean ± standard deviation.

The correlation between FEV1 and FVC values in absolute terms and the FEV1/FVC ratio measured by the two devices were analysed by calculating Pearson's correlation coefficient (r) and were represented by scatterplots with a regression line. Kappa statistics were employed to evaluate overall agreement and agreement based on the severity of airway obstruction between devices, using an FEV1/FVC <70% threshold for defining obstruction. The analysis utilized Cohen's kappa test to compute the kappa coefficient (κ), providing a measure of diagnostic agreement strength. Kappa values were categorized and shaded to represent different levels of agreement: 0.4-0.6 for moderate agreement, 0.6-0.8 for substantial agreement, and 0.8-1.0 for almost perfect agreement.(Branger s. d.),(McGinn *et al*. 2004)

RESULTS

Description of the population

A total of 222 individuals, aged 37 to 86 (mean age 59.2 ± 10.4 years), 63.1% were female, 33.3% were smokers, 29.4% had occupational exposure (gas, smoke, dust...), 23.9% had

Table 1 This table shows the results of the descriptive analysis and the bivariate analysis between the obstructive ventilatory disorder detected by Air-Smart and other socio-demographic and clinicalfactors.

Variables	N (%) OR M(± SD) (N=222)	OVD Air-Smart		p-Value
		Yes	No	
		88 (39,6%)	134 (60,4%)	
Age(M±SD)	59,27 ± 10,4	61,3 ± 10,6	58,2 ± 10,1	**0,026**
Gender				
Female	140 (63,1%)	54 (38,6%)	86 (61,4%)	0,67
Male	82 (36,9%)	34 (41,5%)	48 (58,5%)	
Smoking				
Yes	74 (33,3%)	35 (47,3%)	39 (52,2%)	0,09
No	148 (66,7%)	53 (35,8%)	95 (64,2%)	
Professional exposure				
Yes	65 (29,4%)	24 (36,9%)	41 (63,1%)	0,63
No	156 (70,6%)	63 (40,4%)	93 (59,6%)	
Cardiopathy				
Yes	53 (23,9%)	21 (39,6%)	32 (60,4%)	0,99
No	169 (76,1%)	67 (39,6%)	102 (60,4%)	
Diabetes				
Yes	44 (19,9%)	16 (36,4%)	28 (63,6%)	0,65
No	177 (80,1%)	71 (40,1)	106 (59,9%)	
High blood pressure				
Yes	45 (20,4%)	16 (35,6%)	29 (64,4%)	0,51
No	176 (79,6%)	72 (40,9%)	104 (59,1%)	
BMI(M±SD)	27,4 ± 6,8	25,4 ± 7,2	28,6 ± 6,3	**0,001**
Cough				
Yes	90 (40,7%)	38 (42,2%)	52 (57,8%)	0,47
No	131(59,3%)	49 (37,4%)	82 (62,6%)	
Expectorations				
Yes	74 (33,5%)	33 (44,6%)	41 (55,4%)	0,26
No	147 (66,5%)	54 (36,7)	93 (63,3%)	
Dyspnea				
Yes	117 (53,2%)	48 (41,0%)	69 (59,0%)	0,63
No	103 (46,8%)	39 (37,9%)	64 (62,1%)	

***BMI:** Body Mass Index
***OVD:** Obstructive ventilatory disorder
***M:** Mean
***SD:** Standard deviation

Table 2 this contingency table illustrates the classification of the severity levels of obstructive ventilatory disorder according to the two spirometers.

		Easy-One					
		No obstruction	**Stage I**	**Stage II**	**Stage III**	**Stage IV**	**Total**
Air-Smart	**No obstruction**	126	2	4	2	0	134
	Stage I	10	5	6	2	0	23
	Stage II	14	1	10	3	1	29
	Stage III	6	0	2	15	3	26
	Stage IV	2	0	0	2	6	10
	Total	158	8	22	24	10	222

heart disease, 19.9% were diabetics, and 20.4% were hypertensive. In our sample, cough was present in 40.7% of participants, sputum in 33.5% and dyspnoea in 53.2%.

Correlation analysis

Data showed a strong correlation between absolute values of FEV1, FVC and FEV1/FVC ratio measured with the Smart Air mobile spirometer and conventional office spirometry, with r= 0.87 (p<0.001), r= 0.84 (p<0.001) and r= 0.75 (p<0.001), respectively.

Prevalence of obstructive disorders

In our sample, Air-Smart detected 88 (39.6%) participants with obstructive ventilatory disorder (OVD), of whom 56 (63.6%) had OVD confirmed by conventional spirometry (Easy-one).

Among 64 (28.8%) participants confirmed to have OVD by the standard spirometer, the Air-Smart revealed 56 (87.5%) with OVD.

Positive and negative predictive value

For the detection of airflow obstruction, the portable device had a PPV of (63.6%) and NPV of (94.0%).

Kappa analysis

Overall agreement between the two devices in detecting obstructive ventilatory disorder using a threshold < 0.70% as the "gold standard" for defining obstruction shows substantial agreement, Kappa coefficient(K)=0.61 (95% CI (0.55; 0.67)).
The Kappa coefficient between the two devices according to spirometric classification of obstruction severity stages was 0.5 (95% CI (0.43; 0.56)), reflecting moderate agreement.

Factors associated with the obstructive syndrome detected by Air-Smart

In the bivariate analysis, TVO was associated with older age ((m=61.3 vs m=58.2y) p=0.026), and lower body mass index (BMI) ((m=25.4 vs m=28.6) p=0.001), but there was no statistically significant association with other factors.

DISCUSSION

The portable spirometer plays a crucial role in screening and monitoring chronic obstructive pulmonary disease (COPD), assessing key lung function parameters such as exhaled air volume, exhaled air velocity, and the FEV1/forced vital capacity (FVC) ratio. This aids in the early detection of airway obstruction, even before clinical symptoms of COPD manifest. Furthermore, it serves as a tool to classify the severity of COPD, assisting healthcare professionals in determining the disease stage and formulating an appropriate treatment plan.
A notable example of such a portable spirometer is the Smart Air spirometer, which has garnered significant attention recently. This innovative ultra-portable device conducts spirometric measurements by connecting to a smartphone or tablet through the headphone jack. The Smart Air spirometer presents an appealing and cost-effective solution for the widespread adoption of spirometry, not only in primary care settings but also within the comfort of patients' homes.
The aim of this study was to investigate the diagnostic capability of the new portable spirometer (SMART-AIR) compared with a standard spirometer for COPD screening in a restricted group of consultants'scompanionsin the pulmonology department at the Hassan II university hospital in Fez, so that it could be used in general population screening.

Data showed a strong correlation between absolute values of FEV1, FVC and FEV1/FVC ratio measured with the Smart Air mobile spirometer and conventional office spirometry, with r= 0.87, r= 0.84 and r= 0.75, respectively. This is consistent with a study conducted in South Africa. (Du Plessis *et al*. 2019b), which reports optimal correlation between parameters.

In our study, among the total participants, the Smart Air spirometer identified 88 individuals (39.6%) with obstructive disease. Specifically, among the 64 participants diagnosed with obstructive disease by the standard spirometer, the Smart Air spirometer detected 56 cases (87.5%). These findings align with the outcomes of the Smart Air validation study conducted by Hernandez *et al*.(Ramos Hernández *et al*. 2018), where an FEV1/FVC ratio <0.7 served as the "gold standard" for identifying obstruction.

The degree of agreement between the two devices was quantified using the Kappa index, revealing substantial agreement with a value of K=0.61. It's noteworthy that this figure, while indicative of a good level of agreement, falls short of the very high concordance observed in the Hernandez study (K=0.88) (Ramos Hernández *et al*. 2018), A comparison with the results of another Chinese study examining a different portable spirometer (D-PNEU)(Chen *et al*. 2018). also indicates a lower level of concordance in our study. One plausible explanation for this disparity is that both the Hernandez study and the Chinese study focused on patients already diagnosed with lung disease, in contrast to our study, which was conducted on a population of healthy individuals. This fundamental difference in study populations could contribute to variations in spirometer performance and diagnostic outcomes.

The assessment of concordance between the two devices regarding the spirometric classification of obstruction severity stages yielded a moderate Kappa index value of 0.5 in our study. while overall concordance was moderate, there was observed good concordance specifically for advanced stages (stage III and IV) of obstruction. This finding contrasts with the study conducted by Chen *et al*., which reported almost perfect concordance for the classification of obstruction stages.(Chen *et al*. 2018)

The disparity in concordance between our study and the study by Chen *et al*. could be attributed to various factors. One potential factor is the inherent variability in study populations and the distribution of disease severity within those populations. Differences in participant demographics, health status, and prevalence of advanced stages of obstruction may contribute to variations in the performance of the spirometric devices.

The discrepancy with the findings of Chen *et al*. emphasizes the need for a nuanced interpretation of results, considering the diverse factors influencing concordance in spirometric assessments across different studies and populations. In our current context, a study is underway to validate the Air-Smart spirometer, notable findings have emerged. The sensitivity of the spirometer is impressively high at 89.3%, indicating its efficacy in correctly identifying individuals with obstructive disease. However, there is a small percentage of false negatives, raising concerns about potential complications in cases where the spirometer fails to detect them.

Conversely, the specificity of the Air-Smart spirometer is somewhat lower, standing at 74.6%. This suggests a higher likelihood of false positives, implying that some individuals may be incorrectly identified as having obstructive disease. It is important to note that these false positives will be subsequently verified by a reference diagnostic test, mitigating the potential impact on participants.

In the broader context, these variations in sensitivity and specificity do not significantly impact the study participants. However, it emphasizes the need for caution in interpreting the results and underscores the importance of corroborating

spirometric findings with a standard spirometer. While mini-spirometers like the Air-Smart show promise, they are not standalone tools for comprehensive COPD screening. The integration of standard spirometry remains crucial for a more thorough and accurate assessment.

CONCLUSION

This study was considered preliminary to assess the feasibility of COPD screening using the new Air Smart spirometer and showed good measures of correlation and with the conventional spirometry. The Air Smart could be an exciting and affordable tool for screening purposes in the primary care setting.These results have major implications for a healthcare system with limited resources that serves a large population, where spirometry is not widely available.

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