The predictive value of handheld peak expiratory flow metre and IPAG questionnaire as a screening tool for COPD among high-risk patients

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ABSTRACT

Introduction: Chronic Obstructive pulmonary Disease (COPD) is increasing in Africa due to multiple risk factors like smoking and use of biomass fuels'. There are challenges in the diagnosis of COPD at primary care due to scarcity of spirometers.

Aim: The objective of the study was to evaluate the predictive value of peak flow rate obtained from a hand-held PEFM and questionnaire as a screening tool of COPD among high risk patients.

Methodology: A cross-sectional study was carried out from August to November 2018. One hundred and Ninety (190) participants with risk factors for COPD were recruited at the Family Medicine Department in LASUTH, Lagos State. The history of risk factors, International primary airway group (IPAG) questionnaire scores, Peak Expiratory Flow Rate (PEFR) and Spirometry values captured. The best cut-off for PEFM as a screening tool was assessed using ROC curve. Results: PEFM had a Sensitivity of 82.3%, Specificity of 51.1%, and PPV of 63.2% and NPV of 73.8%. The IPAG questionnaire reported sensitivity (44.8%) and specificity (23.4%) indicating poor detection rates of COPD when used as a screening tool. Combining the use of a questionnaire and peak flow meter, less than half (43.8%) of those with COPD would be identified. .ROC revealed best cut off for PEFR as 79.5% of expected which would give a sensitivity of 81.3% and specificity of 57.7%.

Conclusion: The mechanical handheld PEFM was determined to have a high sensitivity and PPV, with moderate NPV making it a useful tool in screening for COPD especially in primary care settings where spirometry may not be available.

Keywords: Peak flow Meter, Peak Expiratory flow Rate, Spirometry, COPD

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is characterized by persistent respiratory symptoms and airflow limitation due to airway abnormalities caused by significant exposure to noxious stimuli and air pollution.[1] COPD is now recognized as a major health problem in low- and middle-income countries (LMICs),[2] unlike the perception that it occurs only in high income countries. In 2019, COPD was the third single cause of mortality worldwide with 3.8 million deaths and approximately 90% of these occurring in LMICs.[3] A study carried out in Nigeria as part of the Burden of Obstructive Lung Disease (BOLD study) reported a prevalence for COPD of 7%.[4]

Cigarette smoking has been identified as the most important risk factor for COPD.[1,2] There are other risk factors including biomass pollution, genetic factors, ageing, gender and infections like pulmonary tuberculosis.[1,5] Infections like Tuberculosis alongside the use of fossil fuels is projected to increase the number of persons with COPD in Africa.[6,7]

In this study, persons with risk factors described above are described as high-risk patients for COPD. COPD diagnosis can be missed in the early stages as symptoms are frequently attributed to ageing and respiratory infections.[8,9] Spirometry is recommended as a diagnostic tool in the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines.1The underdiagnosis of COPD is worsened by the under-use of Spirometry in primary care.[10] In Africa, there is a

recognized challenge of unavailability of Spirometers and the shortage of trained personnel to use them. [11-13] Hand held mechanical Peak Expiratory Flow Meters (PEFM) are already being used at the level of primary care especially in the management of asthma, but not for COPD. A screening cut off of <80% of the expected PEFR had been suggested as a cut-off for screening COPD.[14-17] The combination of using Peak Flow Meters with the use of questionnaires to increase detection rates in high risk patients has been advocated.[13,15,17]

Due to the increasing prevalence of COPD, alongside the challenges associated with the availability and use of Spirometry,[18,19] there is a need for studies which would assess the usefulness of handheld PEFM in diagnosing COPD especially in high risk persons. During the course of the literature search, there was a paucity of data on using handheld PEFM as screening tool for COPD especially in Nigeria. PEFM could therefore be an important tool for screening patients at risk of COPD if found to be useful. The aim of the study was to study the reliability of hand-held mechanical Peak Expiratory Flow meter to detect COPD in patients at high risk of developing COPD.

METHODOLOGY

Study Area: The General Outpatient Clinic of the Department of Family Medicine, Lagos State University Teaching Hospital (LASUTH), Ikeja, Lagos State was the site of this study. LASUTH is a training, research and referral centre. It has a total number of 756 beds and is still expanding with ultra-modern equipment. The clinic provides primary and secondary (acute care and long-term treatment). The General Outpatient Clinic acts as a referring point for patients that need specialist care. The annual attendance at the clinic is about 78,000 with a monthly average of 6,500. The clientele is undifferentiated in terms of gender, age and financial capacities. Enrolment in the clinic does not require a referral letter; leading to easy access. A review of the clinic attendance records showed that about 200 patients with respiratory symptoms are seen at the Family Medicine Clinic, LASUTH every month with an average of 10 per day.

Study Design: It was a descriptive cross-sectional study Study Population: Patients seeking medical care for respiratory illness were recruited between August and November 2018.

Sample Size: This was determined with the equation for calculating the minimum sample size in epidemiological studies as follows: [20]

$n=Z^2pq/d^2$

Where n denotes the sample size for population >10,000;

Z -standard deviation at 95% confidence interval which is 1.96

P -prevalence (which is 13.6%, the prevalence of COPD from Metanalysis in Africa) 21

q=1-p (which is 1- 0.136=0.864)

d represents the desired accuracy which is set at 95% confidence interval i. e. 1 – 0.95=0.05.

Substituting into the formula above:

$$n= \frac{1.96^2 \times 0.136 \times 0.864}{0.05^2} = 180$$

To increase the power of the study, 190 participants were recruited and participated.

Inclusion Criteria

1) Participants aged ≥40 years of age.
2) Participants who had smoked cigarettes and marijuana (current and in the past).
3) Participants who had completed treatment for tuberculosis (with negative sputum results)
4) Participants who worked in Industries using chemicals and wood (Occupational hazards).
5) Participants who presented with recurrent history of cough for at least 3 months in the year with phlegm production and dyspnea.
6) Participants who used biomass fuels (wood) for cooking.

Exclusion Criteria

1. Participants diagnosed of obstructive lung disease or any chronic respiratory disease.
2. Participants who were unable to perform or had contraindications to the use of spirometry or peak expiratory flow meter due to age, active tuberculosis etc.
3. Pregnant women
4. Participants who required emergency care.

Study procedure: Participants seeking medical care at the general outpatient clinic who met the selection criteria were recruited consecutively into the study after giving their consent until the required sample size was gotten. Due to the need to carry out spirometry and fill the questionnaire,[4] participants were recruited daily, and in cases where a recruited participant could not carry spirometry, a replacement was recruited. All participants had a peak expiratory flow meter and spirometry carried out by a trained physiologist in the hospital after being the administration of the questionnaire. The PEFR was measured using Wright's peak expiratory flow meter after the participants had been taught how to use it. The best of three attempts at peak flow rate was recorded. The Spirometry was done using a validated

vitalograph Gold Standard Spirometer which was available in LASUTH, Ikeja. The Spirometry measurements were performed pre and post (30mintes) after inhalation of 400mcg salbutamol via a metered dose inhaler.

Ethical Consideration: Participation in the study was voluntary. The aim of the study was explained to the participants and written informed consent was obtained from participants. They were informed of their right to refuse participation, or to withdraw at any time they so wished and that their care would not be affected by way of sanctions or repercussions. The ethics committee of the Lagos State University Teaching Hospital, Ikeja gave ethical approval with reference LREC 06/10/51.

Data Collection Instrument: This was accomplished through the use of interviewer-administered, structured questionnaire. The questionnaire consisted of four parts.

Part A obtained information on the participants' age, sex, tribe, religion, marital status, educational status, income, cooking method, and co-morbid condition. Biomass Fuel was classified as the use of charcoal, kerosene, and firewood in this study.

Part B obtained information as contained in the International Primary Airway Guideline Questionnaire on COPD with the total score calculated from the scoring system. A scoring system of ≤17 indicated a diagnosis other than COPD while a score of >17 was suggestive of COPD.[22] Cigarette consumption in pack-years was calculated (pack-years= average number of cigarettes per day x years of smoking/20).

Part C : obtained the details of the physical examination, including the blood pressure, weight in kilograms, height in meters and body mass index in kilograms/meter. The blood pressure was recorded in the consulting room after 5minutes of rest using a validated automated sphygmomanometer (OMRON 705IT). Using appropriate cuff size, each participant was placed in the sitting position with the feet flat on the floor and arm placed at the level of the heart. The blood pressure was measured three times and the average blood pressure recorded. An average of triplicate measurements was used. The weight was measured without shoes using a calibrated standard weighing scale (FAZZINI, made in Italy) and the height was measured without shoes with a fixed wall-type calibrated 3-meter rule and the patient standing upright. Using the weight and height, the body mass index (BMI) was calculated using the formula weight/height (kg/m2).

Part D recorded the findings on Peak Expiratory flow rates and Spirometry results. The participants predicted peak expiratory flow rate percentage was calculated using published reference equations which incorporated the age, height, weight and gender of the participant.[23] The percentage was then calculated from the reference against the obtained values and participants with ≤80% of expected were grouped as COPD and >80% as not having COPD.14-17An obtained post bronchodilator FEV1/FVC <0.7 was defined as COPD patients.[1]

Outcome Measures:

a) The Peak flow rate of < 80% of expected by the Wright peak flow meter was used as screening cut-off for COPD.[14-17]
b) The International primary care airway group (IPAG) questionnaire was used as a screening tool with values >17 used as a cut-off for COPD.[15-16]
c) Spirometry values FEV1 /FVC < 0.7 after bronchodilation (15-30 minutes after 400µg of salbutamol) was a definitive diagnosis of COPD. The staging of COPD was also calculated using FEV1 when COPD was confirmed.[1]

Data Analysis: The data analysis was performed using the SPSS 22 (Statistical Package for the Social Sciences). Computations, tabulations, percentages and other summary statistics were performed. The sensitivity, specificity, negative predictive value and positive predictive values of peak expiratory flow rate and IPAG questionnaire compared to the gold standard of Spirometry were calculated. Multiple linear regression was used to assess to the relationship between the IPAG questionnaire and peak expiratory flow rates with spirometry rates. The best cut- off for observed predicted peak expiratory flow rates as screening for COPD was found using the ROC curve. Funding: The research was funded by the researchers. All investigations were paid for by the researcher.

RESULTS

Table 1 depicts the mean age of the participants was 55.06 ± 10.3 years with the 40-49 age group in the majority (37.9%). More than half (53.7%) of the respondents were female with a majority (85.3%)

Table 1 Showing Socio-Demographic Characteristics of the Participants

Variable	Frequency(N=190)	Percentage (%)
Age		
40-49	72	37.9
50-59	53	27.9
60-69	46	24.2
70-79	15	7.9
>80 years	4	2.1
Mean Age (yrs.): 55.06± 10.3		

Gender		
Male	88	46.3
Female	102	53.7
Religion		
Christian	143	75.3
Muslim	45	23.6
Traditionalist	2	1.1
Occupation		
Employed	162	85.3
Unemployed	22	11.6
Retired	6	3.1
Marital Status		
Married	177	93.2
Single	9	4.7
Widow/Widower	3	1.6
Separated	1	0.5
Income (Naira)		
<50,000	122	64.2
50-100,000	35	18.4
>100,000	33	17.4
Presence of Co-morbid		
Condition	100	52.6
No	90	47.4
Yes		
Body Mass		
Index(Kg/m2)	7	3.7
Underweight	65	34.2
Normal	65	34.2
Overweight	53	27.9
Obese		
BMI(Mean)		
27.59±6.34		
Working in		
Dusty/		
Chemical	74	38.8
Environment	116	61.2
No		
Yes		
Mean		
Duration(Years)		
10.88± 9.78		
Use of Biomass		
Fuel in the Past		
No	62	25.8
Yes	128	74.2

N=190

More than a third (37.4%) of participants had a history of smoking, whilst about 15% of respondents had a history of tuberculosis. A majority of respondents had used fossil fuel and worked in a dusty/ chemical environment as shown in table 2.

Table 2 Risk Factors for COPD Among Participants

Risk Factor	Frequency (N)	Percentage (%)
Smoking (Past and Current)		
No	120	62.6
Yes	70	37.4
Mean duration of smoking (pack yrs.)		
7.67± 11.57		
Past History of		
TB	162	85.3
No	28	14.7
Yes		

The prevalence of COPD was 34.2% and 65.8% as detected by the use of screening questionnaire and Peak flow meter respectively while 50.5% of participants had COPD as confirmed by spirometry as shown in figure 1.

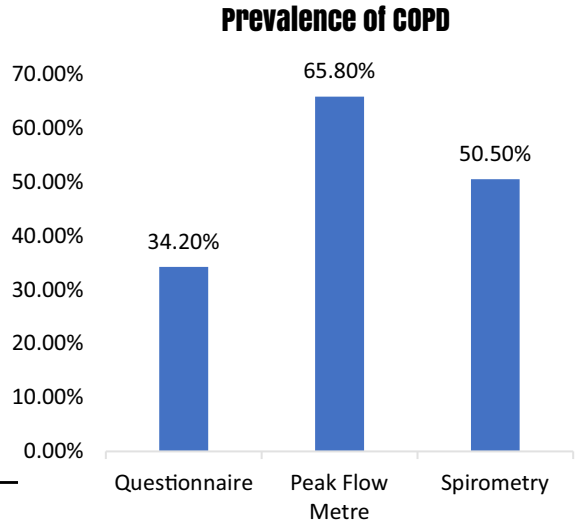


Figure 1: Bar chart showing Prevalence of COPD as assessed by Screening Tools and Gold Standard (Spirometry)

employed. A majority of the respondents were married (93.2%) and about two third (64.2%) earned less than 50,000 naira as shown in table 1.

A majority (82.3%) of those with the disease would be identified by using the Peak Flow Meter whilst about half of those without the disease (51.1%) would be identified. The PPV (63.2%) and NPV (73.8%) indicates only few false positives and negatives respectively. The IPAG questionnaire showed poor sensitivity (44.8%) and specificity (23.4%) indicating poor detection rates of COPD when used as a screening tool. Combining the use of a questionnaire and peak flow meter, less than half (43.8%) of those with COPD would be identified, whilst 58.5% of those without COPD will be identified. The PPV and NPV also showed

Table 3 : Screening of COPD using IPAG Questionnaire and Peak Flow Meter

	IPAG Questionnaire	PEFR	Combination of IPAG and PEFR
Sensitivity (%)	44.8	82.3	43.8
Specificity (%)	23.4	51.1	58.5
PPV (%)	66.2	63.2	51.9
NPV (%)	42.4	73.8	56.5

Both the IPAG questionnaire and PEFR had a significant relationship with FEV1/FEV (p <0.001). However, PEFR had a more predictive value of COPD (β = 0.350) compared to the IPAG questionnaire (β = 0.247) as shown in Table 4

Table 4: Multiple Linear regression of IPAG Scores and Peak Expiratory Flow Rates with FEV1/FVC

Variable	Unstandardized Coefficient		Standardized Coefficient	T	p	95%CI for B
	β	Standard Error	Beta			
Constant	65.787	3.059		21.506	0.000	59.752 – 71.822
Questionnaire scores	-0.533	0.142	-0.247	-3.7609	0.000	-0.812 – -0.253
PEFR	0.037	0.007	0.350	5.320	0.000	0.023 – 0.051

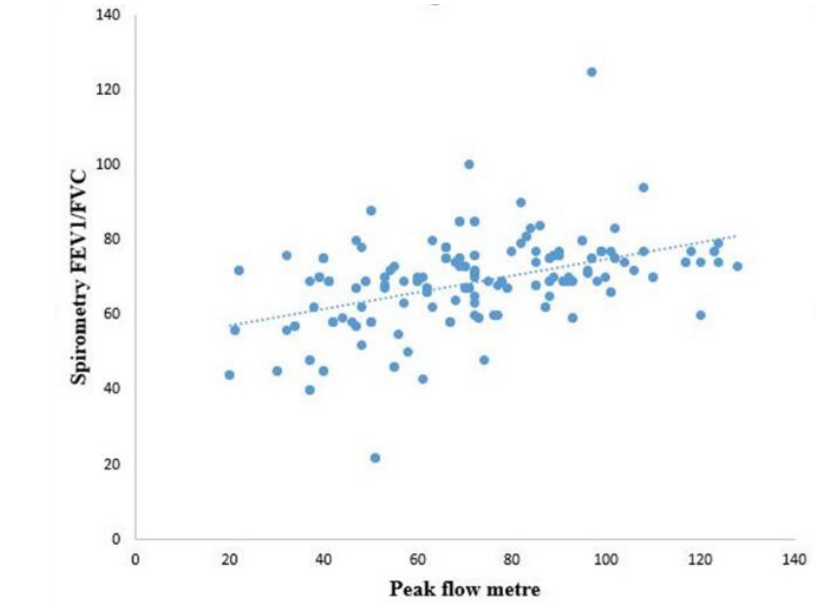


Figure 2: Correlation between Spirometry pattern and IPAG Scores

There is a negative correlation (p-<0.001, r- 0.247) between IPAG scores and FEV1/FVC as shown in figure 2.

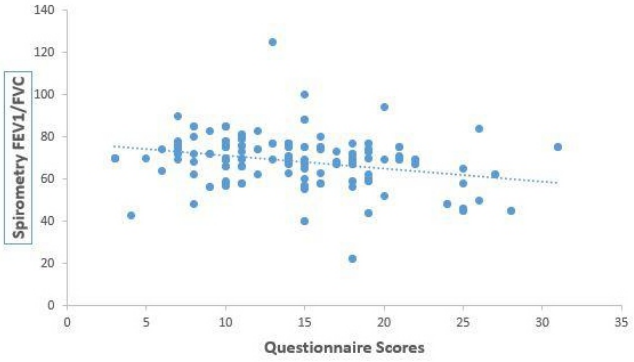
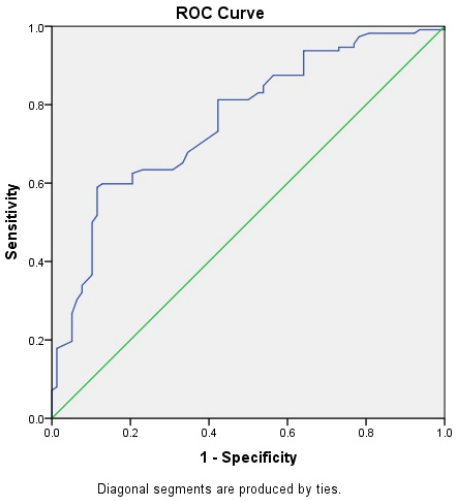


Figure 3 Correlation between Spirometry pattern and Peak flow Rates

There is a negative correlation (p-<0.001, r- 0.247) between IPAG scores and FEV1/FVC as shown in figure 3.



The positive actual state is FEV1/FVC <70%

Figure 3 Receiver Operating Curve comparing PEFR against Spirometry

The curve is to the left of the tangent line indicating a relationship between the sensitivity (True positive rate) and 1-specificity (False positive rate) as shown in figure 3. The best cut off was 79.5% which would give a sensitivity 81.3% and specificity 57.7% as depicted by figure 3.

The curve is to the left of the tangent line indicating a relationship between the sensitivity (True positive rate) and 1- specificity (False positive rate) as shown in table 4. The best cut-off was 79.5% which would be a sensitivity of 81.3% and specificity of 57.7% as depicted by table 4. The area under the curve is 0.760 with a significant p-value 0.000 indicating a fair accuracy of PEFR in diagnosing COPD as shown in table 5.

Table 5 Area Under the Curve of the ROC Curve

Test Result Variable(s): PrePEFRper				
Area Under Curve	Std Error *	Asymptomatic Sig	95% Confidence Interval	
			Lower Bound	Upper Bound
0.760	0.035	0.000	.692	.892

*Non-parametric assumption

high levels of false positive and negative results as shown in table 3.

The area under the curve is 0.760 with a significant p-value 0.000 indicating a fair accuracy of PEFR in diagnosing COPD as shown in table 5. N=190

Discussion

The prevalence of COPD among participants in this study was 50.5% with majority having mild to moderate severity. The prevalence value from this study is higher than worldwide average of 10.1% from the BOLD Study.[4] It is also higher than the prevalence in African region,[21] which has ranged from 3.6-22 %. The difference in prevalence may be due to the study location, the study participants and the diagnostic criterion used in this study. The prevalence of COPD has also been reported to be higher in urban areas, [6,24] and the use of FEV1/FVC <0.7 gives a higher prevalence of COPD as against FEV1/FVC LLN.[25,26] Studies which have reported high prevalence of COPD include Danish,[27] with 36% and Mexico,[28] with 20.6% and they recruited participants exposed to risk factors (smoking, biomass fuels etc) as inclusion criteria.

The sensitivity, specificity, PPV and NPV values obtained for PEFM in this study were lower than that reported by Perez Padilla,[12] Thorat,[17] and Mahboub et al.[28] The peak expiratory flow rate obtained from these study designs used spirometry, and not a mechanical peak flow meter. Also, Jitho et al reported that the sensitivity of PEFM would increase in moderate-severe cases of COPD.[22]

Studies which have used a handheld mechanical PEFM as a screening tool by Tian et al in China,[30] and Jackson et al,16 also reported higher sensitivity and specificity rates. The reference PEFR values used in these studies were calculated for the local populations studied, while this study used reference values for adults in general. However, the PEFR obtained in this study still has a high sensitivity which would help in detecting those with COPD, while the PPV and NPV means that those screened have and do not have the disease respectively.

The IPAG questionnaire sensitivity and specificity were poor in detecting COPD. A meta-analysis of the diagnostic accuracy of the IPAG questionnaire reported a sensitivity of 87.5%, specificity 38.8%, positive predictive value 7.7%, and negative predictive value 98.2%,[31] however the IPAG questionnaire performs better among those with significant smoking history, but the participants in this study reported non-significant smoking history (less than 10 pack years). The values obtained from this study would suggest that the questionnaire missed detecting majority of participants with COPD, though the PPV means that participants with higher IPAG scores would likely have COPD

The IPAG questionnaire and PEFM when used together had a reduced sensitivity, specificity, NPV and PPV. This is different from the reported findings in a US study where an increase in sensitivity and specificity was observed when the Peak Flow Rate was combined with a screening questionnaire.[32] However the CAPTURE questionnaire was used which is mainly symptom-based and does not assess risk factors like the IPAG used in this study.

The PEFR had a more predictive value of COPD (β = 0.350) compared to the IPAG questionnaire (β = 0.247) in this study., with the observation that the participants with COPD had lower PEFR values. This is in keeping with a similar finding in a cross-sectional study carried out in Dubai[29] A study carried out in the United States also reported that PEFR was significantly correlated with spirometry values (p< 0.0001), including FEV1 (r = 0.82), FEV1 percent predicted (r = 0.70), and FEV1/FVC ratio (r = 0.64),32this was the same finding in this study.

A ROC curve of PEF values and FEV1/FVC ratio gave the best cut-off for PEFR of 79.5% which would give a sensitivity of 81.3% and a specificity of 57.7%. The ROC curve gave an area under the curve of0.760, which indicated a fair accuracy of PEF as a screening test for COPD. Studies which have assessed PEF <80% as a screening tool for COPD reported AUC of 0.85,[14] 0.76,[12] 0.87,[32] and 0.879,[30] and indicates that PEF <80% can be used for screening COPD.

Limitations: There was a risk of recall bias especially for the exposure to risk factors. It was a hospital-based

study which might affect generalization of the findings to general population. The diagnostic criteria could have affected the results as some guidelines suggest that thr Lower Limit of Normal FEV/FVC should be used instead of FEV/FVC.

Conclusion: The mechanical handheld PEFM was determined to have a high sensitivity and PPV, with moderate NPV making it a useful tool for COPD especially in primary care settings where spirometry may not be available.

Recommendations for Further Studies: There is need for more research at primary care level especially in the population to get baseline lung function tests for Africans and develop questionnaires which would capture common risk factors for COPD in Africa and Nigeria.

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