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A study to assess the utility of forced expiratory volume in 1 second/forced expiratory volume in 6 seconds in diagnosing obstructive airway disease

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Abstract

According to the Global Initiative for Chronic Obstructive Lung Disease criteria, the ratio of forced expiratory volume in the 1st second (FEV1) and forced vital capacity (FVC) is required to diagnose chronic obstructive pulmonary disease. However, it becomes difficult for all patients to meet the proper criteria. Hence, replacing FVC with forced expiratory volume after 6 seconds (FEV6) can help patients get results early with fewer complications. This study was done to assess whether the FEV1/FVC can be replaced with FEV1/FEV6. A year-long observational cross-sectional study was conducted from January 2022 to January 2023. A total of 227 patients were enrolled from the respiratory medicine department. Demographic details and data from spirometry were recorded. Receiver operating characteristic (ROC) curves were created using the data analysis results. The diagnostic utility of FEV1/FVC and FEV1/FEV6 in the diagnosis of obstructive airway disease was examined. Results obtained in the study showed the average FEV6 was 2.05 with a 0.71 standard deviation. An r^2 value of 0.967 ($p<0.05$) indicated a substantial association between the FEV1/FEV6 and FEV1/FVC ratios. An ROC curve was used to show that FEV1/FEV6 could diagnose FEV1/FVC <70%; the area under the curve was 0.987 (95% confidence interval: 0.971-1.000). It has been found that 0.705 is the ideal cut-off value, resulting in 100% sensitivity and 98.2% specificity. To conclude the study, there was a substantial association between FEV1/FVC and FEV1/FEV6 in the diagnosis of obstructive airway illness. Using FEV1/FEV6, an ROC curve was created, and an ideal cut-off of 0.705 was shown to detect obstructive airway disease. Numerous lives can be saved, and prognoses can be improved by using the FEV1/FEV6 study to identify obstructive airway illnesses more easily, improve compliance, and manage them early.

Key words: spirometry, GOLD, FEV1/FVC, FEV1/FEV6, ROC curve, r2, COPD.

Introduction

Obstructive lung diseases are a growing group of non-communicable diseases that can cause morbidity and mortality. Emphysema, bronchiectasis, and chronic bronchitis are some of the lung diseases that cause obstruction [1]. The definition of COPD, as updated in the GOLD report 2024, is a heterogeneous condition of the lungs characterized by chronic respiratory symptoms, such as coughing, production of sputum, and dyspnea, with or without exacerbations, caused because of abnormalities in the airways or alveoli, which results in persistent and progressive obstruction to the airflow [2].

The prevalence of COPD is particularly high in India because of risk factors such as smoking (both active and passive), occupational dust exposure, aging, exposure to biomass fuels, and indoor and outdoor pollution [3]. Globally, COPD is the third most common cause of death [4]. An excessive contraction of respiratory smooth muscle frequently leads to the constriction (obstruction) of the larger and smaller bronchioles. Airway inflammation causes rapid airway rupture, which reduces airflow, makes exhaling difficult, and necessitates repeated visits to the emergency department or doctor's office. The fast and precise diagnosis of these conditions is essential to their optimal management since it enables timely action and better patient outcomes. However, the range of symptoms, inconsistent clinical presentations, and requirement for accurate diagnostic instruments make identifying obstructive airway illnesses difficult. Coughing, phlegm production, and dyspnea, or shortness of breath, are the most common signs of COPD. Symptoms may not always be accurately recorded by patients [5].

Spirometry is the gold standard for diagnosis [2]. Forced expiratory volume in one second (FEV1) is the maximum amount of air that a person can forcefully exhale in the first second after maximal inhalation, and FEV6 is the amount of air that a person can forcefully exhale over a period of six seconds. The modified Tiffeneau-Pinelli index, often known as the FEV1/FVC ratio, is used to identify obstructive and restrictive lung conditions. It shows the ratio of a person's total forced vital capacity to the percentage of their vital capacity that is depleted in the first second of forced expiration. According to the GOLD-2024 criteria, patients with a COPD history should demonstrate a post-bronchodilator FEV1/FVC of 0.70 or lower to confirm the existence of chronic airflow limitation. The patient must continuously exhale for at least 15 seconds during the FVC maneuver, and minors under the age of 12 must continuously exhale for at least 3 seconds. If there is no airflow for at least one second, the maneuver is deemed acceptable. The exhalation process may need a longer time (sometimes 12 to 20 seconds) in people with COPD who have dynamic compression of their airways. Due to a reduced venous return to the heart, this extended effort may cause weariness, lightheadedness, and, in rare instances, syncope [6].

More attention has recently been paid to using the FEV6 instead of the FVC to diagnose COPD. In developing countries, FEV6 may eventually take the role of FVC as the main screening technique. FEV 6 has become a viable alternative to FVC [7]. Notably, FEV6 has benefits including easier implementation for both patients and technicians, a shorter spirometry test length, and a decreased risk of related problems, such as syncope [8]. The FEV6 maneuver is less taxing than the FVC test and has a distinct termination point at six seconds.

However, their usefulness is limited by the lack of global reference equations. The application of a preset criterion for FEV1/FEV6—such as the well-known GOLD criteria for the ratio of FEV1/FVC 0.70—may not be acceptable in a country like India, where people of different ages, races, heights, and weights coexist. The multilayer likelihood ratios of FEV1/FEV6 and FEV1/FVC have also been assessed in a few studies to identify obstructive airway disease. The correlation of the above 2 ratios has also been done with clinical COPD staging [9]. Nevertheless, there aren't many studies in India assessing the use of FEV6 as a substitute for FVC.

This study therefore assessed the usefulness of FEV1/FEV6 in identifying obstructive airway disease and discovered a correlation between it and the clinical stage of COPD.

Materials and Methods

This study spans an entire calendar year from January 2023 to January 2024 at the Himalayan Institute of Medical Sciences' Respiratory Medicine Department in Swami Ram Nagar, Dehradun (HIMS). Following written informed consent, patients with obstructive airway disorders as determined by the GOLD criteria for COPD were gathered from the Chest Outpatient Department (OPD) at HIMS in Dehradun. This study was approved by the institutional ethics committee.

Study design: Observational cross-sectional study.

Sample size: The minimum number of patients required for statistical significance using the probability-based sample size formula was found to be 227.

$$N = \frac{Z^2_{(1-\alpha/2)} P\,(1-P)}{d^2}$$

Where N = sample size estimated

Z = Z score at 95% C.I. – 1.96

P = prevalence or proportion—18% based on a study by Agrawal S et al. [10]

D = margin of error considered here as 5%

Patients with an age of more than 18 years and all diagnosed cases of obstructive airway disease on spirometry according to GOLD guidelines. (FEV1/FVC < 0.70)(2) were included in the study. Patients in acute exacerbation and active infection or who had excessive anxiety, dementia, hearing impairment, or uncooperative patients or patients with myocardial infarction, facial trauma, deformities, or burns were excluded from the study. The excluded tests included those tests too, which are incomplete before the 6-second time limit or the graph is not acceptable and reproducible.

Study tools

Equipment: Power Cube series Body Plus and Diffusion Plus pulmonary function testing. (GANSHORN – SCHILLER GROUP)

To create reports, LFX diagnostics software was utilized.

The study comprised patients who provided written informed consent and met the qualifying requirements. The institute's Respiratory Medicine department conducted the spirometry. A mass-flow sensor was used to take spirometry data, and the patient's medical history was carefully documented and reviewed. Researchers assessed the acquired spirometry tests' accuracy and reliability in accordance with the ATS recommendations. Three acceptable movements were included in each spirometric measurement, and the reading with the greatest FEV1 and FVC totals was used for additional analysis. This process was also used to calculate the FEV6 value. Receiver operating characteristic (ROC) curves were created using the data analysis results. The diagnostic utility of FEV1/FVC and FEV1/FEV6 in the diagnosis of obstructive airway disease was examined.

The obtained results were interpreted and analyzed using the proper tests of significance. To evaluate the correlation between FEV1/FEV6 and FEV1/FVC, a scatter plot graph was created and regression was used. By creating an ROC curve, the ideal fixed cut-off of FEV1/FEV6 was determined.

Microsoft Excel and IBM SPSS version 22 were used to conduct statistical analysis on the gathered data. Frequencies were used to represent categorical data, and the mean, standard deviation, or median were used to reflect continuous data. It is important to employ the appropriate statistical test when analyzing relationships between categorical variables. Statistical significance has been defined as a p-value of less than 0.05.

Results

Only 17 (7.5%) of the 227 patients in the study claimed never having smoked, whereas 210 (92.5%) of the patients were smokers. Based on the GOLD classification for chronic obstructive pulmonary disease, the majority of individuals (43.2%) had Stage 3, followed by

32.6% with Stage 2, 20.3% with Stage 4, and 4% with Stage 1, as depicted in the pie chart below (Figure 1). The mean FEV6 was 2.05 with a standard deviation of 0.71 and a range of 0.72 to 4.3 in all study participants measured at the same time as FVC was determined. Table 1 shows the demographics of the study participants. Table 2 shows FEV1 / FVC and FEV1/FEV6 of study participants

Correlation of FEV1/FEV6 and FEV1/FVC

A scatter plot of the association between FEV1/FEV6 and FEV1/FVC ratios was constructed before the accuracy analysis, and r2 = 0.967 (p-value < 0.05) was considered statistically significant (Figure 2).

A receiver operating characteristic (ROC) curve for presenting the diagnostic ability of FEV1/FEV6 compared to FEV1/FVC<70%

The area under the ROC curve was determined to be 0.987 (95% C.I., 0.971-1.000). The best cut-off value was 0.705, exhibiting an excellent sensitivity of 100% and specificity of 98.2% (Figure 3).

Discussion

In our study, the mean FEV1 was 1.17 (range of 0.42-2.79 and a standard deviation of 0.50), and the mean FVC was 2.08 (standard deviation of 0.72 and a range of 0.73–4.58). The mean FEV6 was 2.05(with a standard deviation of 0.71 and a range of 0.72 L - 4.3). An average FEV1/FVC% % was 55.75 ± 9.62% (30.29% to 78.08%), and an FEV1/FEV6% of 56.34 ± 9.35 (range of 32.3 to 78) was determined as depicted in Figure 4 and Table 2.

The association between the FEV1/FEV6 and FEV1/FVC ratios was assessed in our study using a correlation analysis, which showed a robust correlation with an r^2 value of 0.967 (p-value < 0.05). This result is consistent with the findings of Singh AK et al.'s study, which found a strong association ($r^2 = 0.93$, $p < 0.001$) between the FEV1/FEV6 and FEV1/FVC ratios. [9] In addition, Rosa FW et al.'s study revealed a strong association ($r^2 = 0.92$) between FEV1/FEV6 & FEV1/FVC [11]. All these results and studies strengthen the belief in the usefulness of FEV1/FEV6 as a feasible alternative to more conventional measures like FEV1/FVC in evaluating pulmonary function.

A ROC curve was used in our study to show that FEV1/FEV6 could identify FEV1/FVC < 70%. It has been determined that the area under the ROC curve is 0.987 (95% C.I., 0.971–1.000). It has been found that 0.705 is the ideal cut-off value, resulting in 100% sensitivity and 98.2% specificity.

Recent studies have indicated that FEV1/FEV6 < 71% and FEV6 < 83% may serve as alternatives to the existing thresholds for obstruction and restriction, respectively. For FEV1/FEV6, their results showed 96.3% negative predictive value, 99.4% specificity, 99.3% positive predictive value, and 95.5% sensitivity [12]. The values of FEV1/FEV6 and FEV1/FVC for patients with COPD have been compared in numerous studies conducted globally. According to Venkatachalam et al. [13], 71.85% was the cut-off figure for FEV1/FEV6. The cut-off was 73% with 95.7% sensitivity, 94.2% specificity, 87.5% PPV, and 97.9% NPV, according to Singh AK et al. [9]. The cut-off for Rosa F. W. et al. (11) was 75%. They found a high connection between FEV1/FVC and the FEV1/FEV6 ratio ($r(2) = 0.92$).

Our study had a few limitations. The calculation of the sample size is not accurate as the prevalence of COPD in Uttarakhand is not known. Secondly, as our study is observational and descriptive and lacks a gold standard for the FEV1/FEV6 value, we could not determine the negative and positive likelihood ratios.

This study was conducted to identify a simple and efficient method—like FEV6—for a more affordable and easier diagnosis of obstructive airway disease. Additionally, the current investigation found that the FEV1/FEV6 ratio of 0.705 had high specificity and sensitivity for identifying OAD. Therefore, the FEV1/FEV6 study can aid in early care, easier identification, and improved compliance with obstructive airway illnesses, improving prognosis and saving many lives.

Conclusions

Participants were recruited for this observational study in order to determine an FEV1/FEV6 threshold that corres ponded to the 70% FEV1/FVC limit. FEV1/FVC and FEV1/FEV6 showed a good connection in the diagnosis of obstructive airway disease. The diagnostic ability of FEV1/FEV6 for detecting FEV1/FVC less than 70% has been demonstrated using an ROC curve, with noteworthy outcomes. For the diagnosis of airway obstruction, the FEV(1)/FEV(6) ratio is a valid substitute for FEV(1)/FVC, especially in primary care screens for high-risk COPD populations. Moreover, FEV(6) can be used instead of FVC when identifying a spirometric obstructive pattern. Its relevance in improving respiratory care practices is highlighted by its ability to increase diagnostic accessibility and accuracy.

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Table 1. Demographics of the study participants.

Sex	164 (72.2%) males	63 (27.8%) females
Age (mean)	60.34 yrs	
Occupation (maximum)	33.9 % - Farmers	
Symptoms	49% - shortness of breath with cough	41% - shortness of breath with chest pain
Mean duration of symptoms	18.25 years ± 9.284 yrs	
Past History	124 (54.6%)	
Family history of disease	8.8% (20)	
History of previous treatment	87.7 %	
History of smoking	210 (92.5%)	
GOLD staging	43.2% stage - 3	32.6% , Stage - 2

Table 2. FEV1/FVC and FEV1/FEV6 of study participants

Pulmonary Function Test	Median	Std. Deviation
FEV1/FVC (%)	55.7555	9.61537
FEV1/FEV6(%)	56.347	9.3579

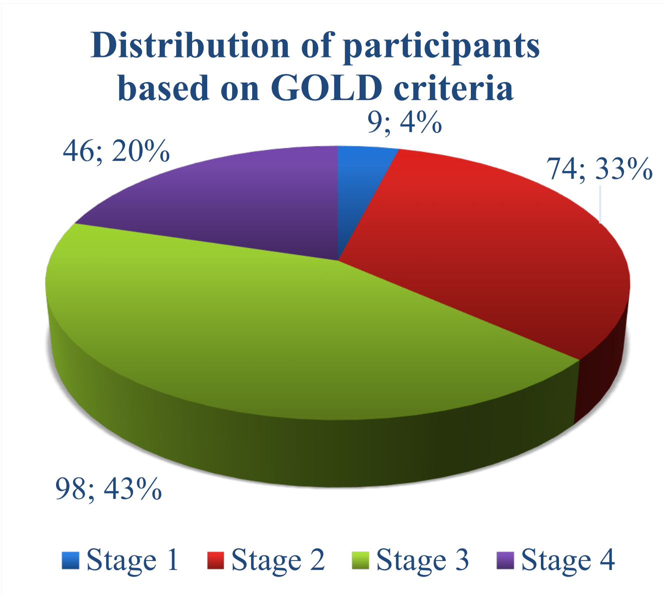

Figure 1. Distribution as per GOLD with highest percentage of patients being in stage 3.

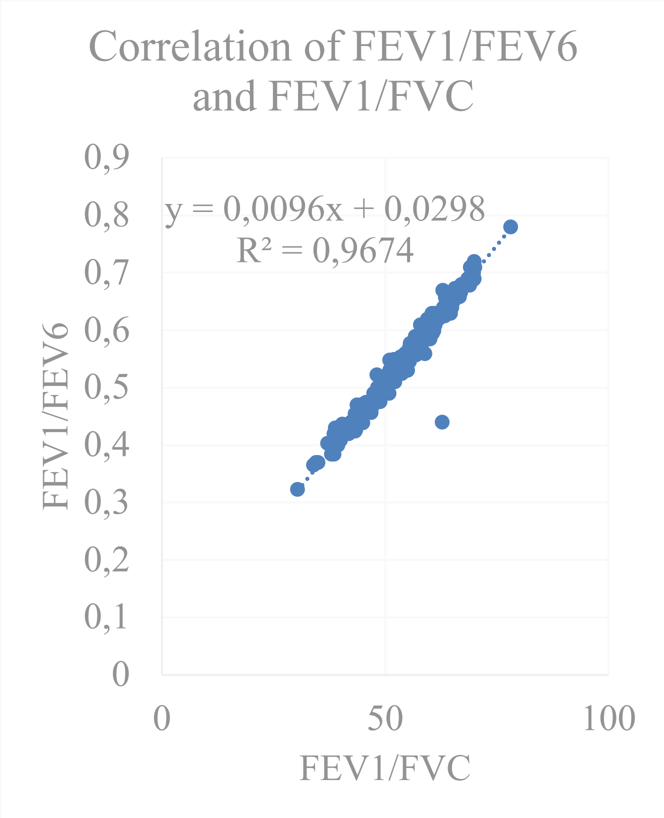

Figure 2. Scatter plot showing significant correlation between FEV1/FEV6 and FEV1/FVC in diagnosing obstructive airway disease.

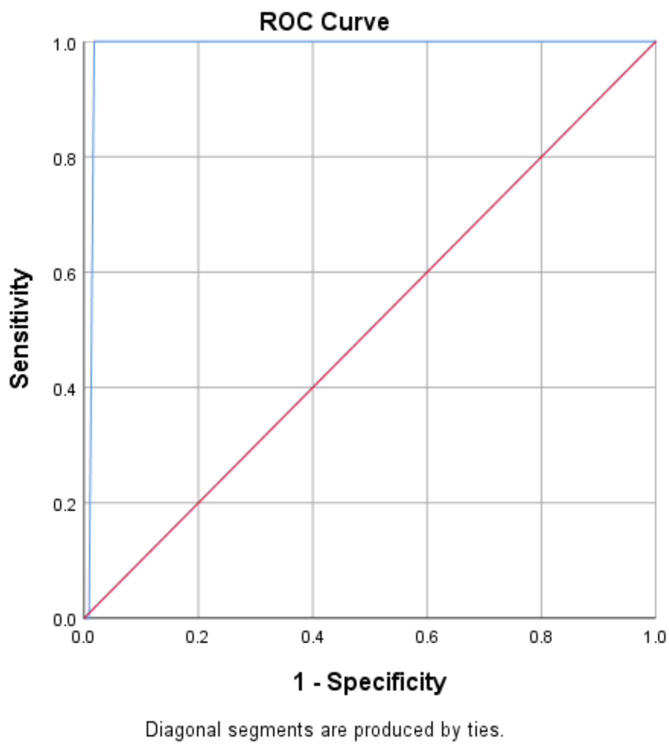

Figure 3. A receiver operating characteristic (ROC) curve for presenting the diagnostic ability of FEV1/FEV6 compared to FEV1/FVC<70%.

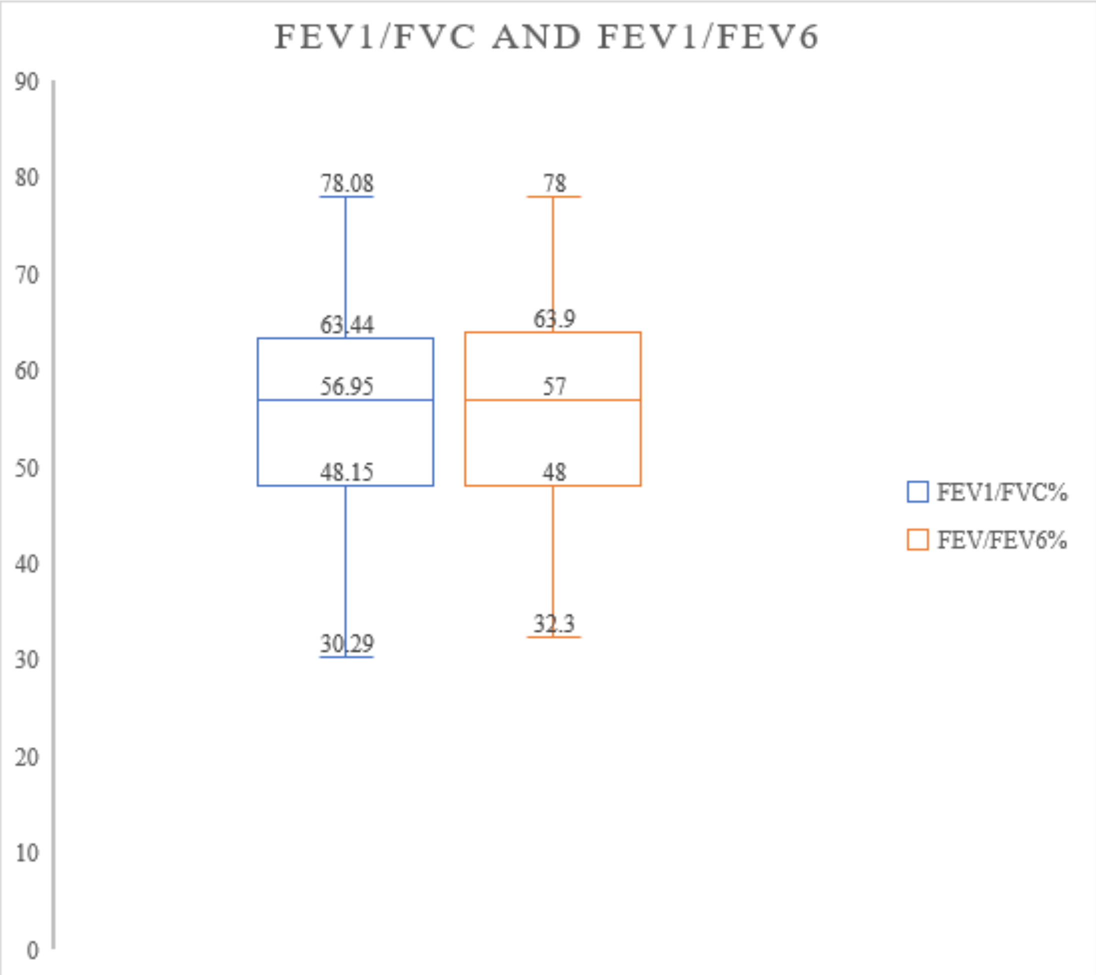

Figure 4. Box and Whisker plot graph showing correlation between FEV1/ FVC% and FEV1/FEV6 % and their medians, respectively.