VALIDITY OF FEV_6, FEV_1/FEV_6 RATIO OVER FEV_1% IN THE DIAGNOSIS OF COPD

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ABSTRACT

BACKGROUND

Conventional Spirometry is the best test for early detection of COPD and the gold standard test for diagnosing COPD as described by American Thoracic Society is FEV_1%. But, the procedure of determining FVC can be uncomfortable for the patients and technicians. FEV_6 has been proposed as a surrogate for FVC as it is easier to perform and offers numerous potential advantages. This study will help us to give a substitute to FEV_1% in the diagnosis of COPD.

METHODS

The study was conducted on 300 subjects of which 190 were COPD patients and 110 normal individuals who attended the Pulmonary Function Laboratory at Government Medical College, Kottayam. The study was done using the instrument Compact Vitalograph. The results were analysed using latest version of SPSS software. The specificity & sensitivity of FEF_6 and FEV_1/FEV_6 ratio was calculated using 2 x 2 tables. The negative predictive value (NPV) and positive predictive value (PPV) was also calculated.

RESULTS

A total of 300 subjects was studied. 220 patients were male and 80 were female patients. 57.2 % are categorized as COPD patients and 42.8 % as normal subjects based on FEV_6 value and 78.60% are categorized as COPD patients and 21.40% as normal subjects based on FEV_1/FEV_6 ratio. 87.6% was the sensitivity of FEV_6 and specificity was 96.4%. The Positive Predictive Value (PPV) & Negative Predictive Value (NPV) were 97.7% and 81.53% respectively. FEV_1/FEV_6 ratio has a sensitivity of 97.9% & specificity of 55.5%. The PPV was 79.49% and NPV of 93.84%.

CONCLUSIONS

FEV_1/FEV_6 with a very high sensitivity and specificity can be used as a diagnostic test. FEV_6 alone also gives a fairly high sensitivity and specificity but the ratio FEV_1/FEV_6 is a better alternative than using FEV_6 alone in COPD diagnosis.

KEY WORDS

Pulmonary Function Test, COPD, FEV_6, FEV_1/FEV_6 Ratio, FEV_1%

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BACKGROUND

Chronic Obstructive Pulmonary Disease (COPD) refers to a group of pathological conditions in which there is chronic obstruction to the airflow at any level from trachea to the smallest airways resulting in functional disability of the lungs. The most standardized and reproducible test for diagnosis of COPD is spirometry and it is a mandatory test to be done on every individual with symptoms of COPD.[1] FEV_1% is a very important investigation in the diagnosis of airway obstruction. But many patients and technicians find the manoeuvre of measuring FVC very exhausting both physically as well as mentally for both the patient and the examiner. In many countries, COPD has grown to be a significant cause for morbidity and mortality among the people.

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So, it became important to find out an acceptable substitute for FEV_1% in diagnosis of COPD. Forced expired volume in 6 s (FEV_6) and the FEV_1/FEV_6 ratio has been proposed by The National Lung Health Education Program, but there are very few data to support this proposal. FEV_6 reduces test time and difficulties of the patient in comparison with measurements of FVC.[2,3,4] Hence, it was hypothesized that using FEV_6 will result in an acceptable low misclassification rate for detecting airways obstruction when compared with using FVC.[5,6]

Aim of The Study

To determine the sensitivity of FEV_6 & FEV_1/FEV_6 ratio as compared to FEV_1% for diagnosing Chronic Obstructive Pulmonary Disease.

METHODS

The present study was performed on 300 subjects of which 190 were COPD patients and 110 normal individuals who attended the Pulmonary Function laboratory at Kottayam medical College. The study was done using the instrument Compact Vitalograph. The study was conducted in the months of June and July. A total of 300 subjects in the age group of 20-60 yrs., were studied (194 COPD and 110 normal). A total of 220 male patients and 80 female patients were included in

the study. The objectives of study and procedure was explained to the subjects in detail.

Study Type
Diagnostic Test Evaluation.

Study Design
Analytical Cross-Sectional Study.

Inclusion Criteria
The subjects included were in the age group of 20-60 yrs, who attended the PFT laboratory for spirometric evaluation during the study period. Patients without medical or any other respiratory illness were included.

Exclusion Criteria
Patients with any other medical or respiratory illness were excluded. Also, patients who did not give consent to the study were excluded.

The procedure of the test was explained thoroughly to the patient and they were made to sit comfortably. The consent was obtained and initial details in the proforma was filled from each patient. Height was measured in centimeters using a scale and weight in kilograms using a weighing machine. Attention was made to ensure that maximal FEV_1 and FVC efforts were obtained. We ensured that at least 6s of expiration was made and no significant cough or other interruption occurred in the test. The subjects were instructed to do the test three times and the best reading among the three was taken into account. The subjects were provided with a sterile mouthpiece.

Sample Size

$$\text{Sample Size} = \frac{4 \times \text{sensitivity}\,(1-\text{sensitivity})}{d^2 \times p}$$

(d-error %, p-prevalence of COPD in India)

Our Equipment
The test was performed using a computerized spirometer called' Compact Vitalograph.' When the subject blows air through the airflow produces a pressure gradient across a flow resistive element which is then converted into electrical signals. These signals can be measured by the computer. The readings are displayed on the computer screen or can be printed on electro sensitive paper for a permanent record. The system is incorporated with ERS 93 software. The software has the provision to calculate FEV_6 and FEV_1/FEV_6 in addition to FVC in the same manoeuvre.

Selection of Tests
To study obstruction in airways, dynamic lung functions were studied. Under dynamic conditions, force is required to overcome the inertia and resistance of tissues and air molecules and also to maintain the lung and chest wall at certain volume. The Vital Capacity (VC) is amount of air that can be exhaled maximally after a maximum inspiration. The normal value of Vital Capacity in men is about 4 litres and in women, about 3 litres. Forced Vital Capacity is the volume of air that can be expired maximally after maximum inspiration as forcefully and as faster as possible. FVC differs very much from VC when there is airway obstruction with air trapping, and it is highly reduced. From FVC, two other important lung functions are obtained: The forced expiratory volume of air exhaled in one second (FEV_1) and the forced expiratory volume in six seconds (FEV_6). The percentage of Vital Capacity expired in 1st second, 2nd second etc. are calculated as FEV_1, FEV_2… FEV_6 and so on.[7,8,9,10]

FEV_1% is considered the best diagnostic tool for COPD diagnosis. But since the procedure of determining FVC is physically exhausting to the patient, there arises the need of finding an acceptable alternative to FEV_1%. Hence FEV_6, FEV_1/FEV_6 ratio. Light et al (1971) systematically evaluated a variety of tests FEV_1, FVC and FEV_1/FVC, FEF25-75% for their ability to separate different broncho dilator regimes of increasing potency. They found that FEV_1 had the highest discriminatory power, followed by FVC. [11,12]

Pulmonary Mechanics Tests
Forced Vital Capacity (FVC)
The volume of air that can be expired maximally after maximum inspiration as forcefully and as faster as possible is Forced Vital Capacity. FVC in men is about 4 liters and in women, about 3 liters normally. FVC differs very little from VC in the normal subject, but it is proportionately more reduced when there is airway obstruction with air trapping. The value of FVC is decreased in obstructive conditions like emphysema and bronchial asthma.

Forced Expiratory Volume (FEV_T)
The fraction of FVC given out in specified time is forced expiratory volume or FEV. The specified time is given in seconds and is written as a subscript to FEV e.g.:-FEV_1, FEV_2, etc. It is usually stated in litres and time in seconds. With the use of appropriate transducers, the instantaneous values of FEV_T directly computed. FEV_T manoeuvre helps us to measure the volume of gas expired over a unit time, the severity of airway obstruction can be confirmed. A low value is obtained in both obstructive and restrictive diseases.

Forced Expiratory Volume in 1st Sec/ Forced Vital Capacity (FEV_1/FVC) %
FEV_T % is the forced expiratory volume for a given interval expressed as a percentage of the forced vital capacity. A normal individual expires 80% of his FVC in the first second, 94% in two seconds and 97% in three seconds. Patients with obstructive disease will show a reduced FEV_T% in majority cases.[13,14,15,16]

Interpretation of Results
Since it is observed that the values of PFTs has got a wide range population, selection of normal values is. So generally, as a rule the results of PFTs of a person is interpreted with respect to predicted values for normal individuals. Predictive normal values are computed by matching with selected physical characteristics like age, height, weight, BMI and sex. Based on the guidelines given by the American Thoracic Society the cut off limit for all the parameters studied under our research were set as 80%. Spirometric values less than 70% for FEV_1% was diagnosed as COPD.[17,18]

Figure 1. Pulmonary Function Testing in The Lab

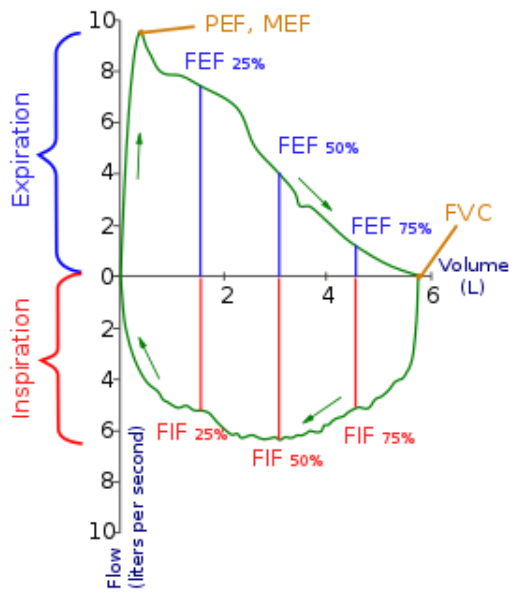


Figure 2. Flow-Volume Loop& Measurement of FVC, FEF & PEFR

RESULTS

Category	Minimum	Maximum	Mean
Age	20	60	56.67
Height	130	188	161.13
Weight	35	100	55.97
BMI	12.30	33.90	21.59

Table 1. Physical Parameters of the Subjects

he subjects studied were between 20 and 60 years with a mean age of 6.67. The mean height was found to be 161.13 and mean weight 55.97. he mean BMI of the subjects was 21.59

	COPD	Normal
$FEV_6 < 80\%$	170	4
$FEV_6 > 80\%$	22	104

Table 2. Sensitivity and Specificity of FEV_6

The Sensitivity of FEV_6 was found to be 87.60%.

The Specificity of FEV_6 was found to be 96.40%

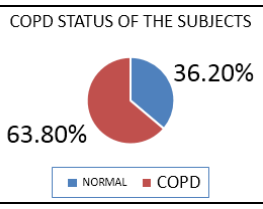
The Positive Predictive Value (PPV) of FEV_6 was 97.70%.

The Negative Predictive Value (NPV) of FEV_6 was 81.53%.

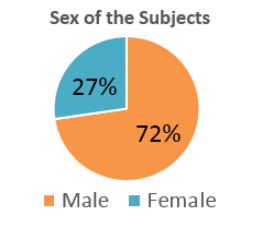
	COPD	Normal
$FEV_1/FEV_6 < 80\%$	190	46
$FEV_1/FEV_6 > 80\%$	4	60

Table 3. Sensitivity and Specificity OF FEV_1/FEV_6

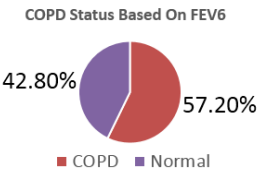
The Sensitivity of FEV_1/FEV_6 ratio was 97.90%. The Specificity of FEV_1/FEV_6 ratio was 55.50%. The Positive Predictive Value (PPV) was 79.49%. The Negative Predictive Value (NPV) was 93.84%.



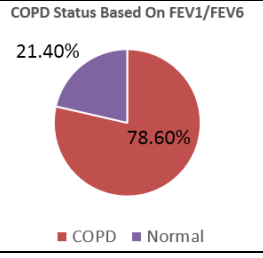
Out of 300 Subjects Studied 63.80% Were Known Cases of COPD and 36.20% were Normal Subjects



72% Were Males and 27% Were Females



Out of 300 Subjects Studied, 57.20% Were Categorized as COPD Patients and 42.80% as Normal Subjects Based on FEV_6 ***Value of Spirometric Examination***



78.60% Were Categorized as COPD Patients and 21.40% as Normal Subjects Based on FEV_1/FEV_6 ***Ratio***

Statistical Analysis

The data was done using Microsoft Excel. For data analysis SPSS of windows version 10 was used. Cross tabulation of the data was done for FEV_6 & FEV_1/FEV_6. Sensitivity and specificity of FEV_1/ FEV_6 & FEV_6 were calculated using 2 x2 tables. The positive predictive value (PPV) and negative predictive value (NPV) were also calculated.

DISCUSSION

Spirometry is a mandatory test in the diagnosis of COPD and according to American Thoracic Society guidelines spirometric values less than 70% for FEV_1% and less than 80% for FEV_6, FEV_1/FEV_6 is diagnostic of COPD. The sensitivity of a test is an index of diagnostic accuracy. It is of a

test to correctly identify all those who are suffering from the disease, that is 'true positive'. The ability of a test to correctly identify those who do not suffer from the disease is called as specificity of a test, that is'true-negatives'. The diagnostic power of the test can also be assessed by' predictive values'.[19,20]

In the present study of 300 subjects referred to the PFT laboratory were studied. Out of the 300 subjects, 190 were diagnosed as COPD and 110 as normal using the Gold Standard spirometric observation 'FEV_1%'. Hence, subjects with FEV_1% less than 70% are diagnosed as COPD while those with value above 70% are categorized as normal.

In the study group 220 (72%) were males and 80 (27%) were females. So, one of our observation was that more males were referred to the lab for spirometric evaluation. We could conclude males were more susceptible to COPD in our area during the study period.

We further categorized the 300 subjects based on the spirometric value obtained for FEV_6 alone. The observation was that 170 subjects (57.20%) fell under COPD category and 130 subjects (42.80%) fell under normal. Hence a total of 20 subjects (6.57%) are underdiagnosed of COPD using FEV_6 value alone. The sensitivity of FEV_6 was found to be 87.60%. Hence, 87.60% of the diseased people screened by the test will give a 'true-positive' result and the remaining 12.40% a 'false negative' result. Also, Specificity of FEV_6 was found to be 96.40%, which means that 96.40 % of the normal subjects will give 'true-negative' result. Only, 3.60% of normal subjects screened by the test will be wrongly classified as COPD subjects when they are not. Besides, FEV_6 has a positive predictive value of 97.70% and a negative predictive value of 81.53%. Hence, 97.70% of subjects who test positive will actually have COPD and 81.53% of subjects who test negative actually do not have the disease. Hence, FEV_6 can be used as an alternative to FEV_1% for COPD diagnosis.

The 300 subjects were categorized into COPD patients and normal subjects based on FEV_1/FEV_6 ratio. The result obtained was that 236 subjects (78.60%) were classified as COPD and 64 subjects (21.40%) as normal. Hence, 45 subjects (14.80%) were misdiagnosed as COPD patients. The sensitivity of the ratio was found to be 97.90%. Hence, 97.90% of the diseased people screened by the test will give a 'true-positive' result and the remaining 2.10% a 'false negative' result. Specificity of FEV_1/FEV_6 was found to be 55.50%, which means that 55.50% of the normal subjects will give 'true-negative' result. But, 44.50% of normal subjects screened by the test will be wrongly classified as COPD subjects when they are not. The positive predictive value is 79.49% and the negative predictive value is 93.84%. It means that 79.49% of subjects who test positive will actually have COPD and 93.84% of subjects who test negative actually do not have the disease. As the sensitivity and negative predictive value of FEV_1/FEV_6 ratio is very high it can be used as a better alternative to FEV_1% in COPD diagnosis especially for screening purposes in high risk populations. Also, the ratio FEV_1/ FEV_6 is found to be a better alternative than using FEV_6 alone.

CONCLUSIONS

FEV_6 alone also has a fairly high sensitivity and specificity but the ratio FEV_1/FEV_6 is a better alternative than using FEV_6 alone in COPD diagnosis. FEV_1/FEV_6 with a very high sensitivity and specificity can be used as a diagnostic test.

Out of the total 300 subjects, 220 (72%) were males and 80 (27%) were females. Since majority of subjects were males, we could conclude that males were more susceptible to the disease in our area during our study period, but this needs more research for confirmation.

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