Comparison of FEV1/FEV6 with FEV1/FVC in the diagnosis of COPD

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ABSTRACT

Background: Globally COPD occurs. But it is a health hazard among those who smoke. The life expectancy is also reduced to a large extent. Hence early diagnosis may help prevent further progression of disease and motivate people to modify their lifestyle.

Methods: Patients aged 40 years and above, attending to pulmonology OPD and in-patients with symptoms suggestive of COPD were subjected to spirometric examinations following standard protocol of test performance as laid down by ATS/ERS. Spirometric examinations were analyzed statistically to know the performance of FEV1/FEV6 ratio using a cut-off value of < 0.70 (post bronchodilator) arbitrarily as against FEV1/FVC ratio of < 0.70 (post bronchodilator) in accordance with GOLD guidelines for the diagnosis of COPD.

Results: Majority (83.8%) were male. Out of 229 patients 197 patients had airways obstruction as per post bronchodilator FEV1/FVC of < 0.70. Among 197 patients who were diagnosed as having COPD as per post bronchodilator FEV1/FVC ratio, 180 (91.37%) patients had an FEV1/FEV6 value < 0.70. Among 192 male patients, 170 were diagnosed as having COPD as per post bronchodilator FEV1/FVC ratio of < 0.70 as against 153 as per post bronchodilator FEV1/FEV6 ratio of < 0.70. Among 37 female patients 27 were found to have COPD based on both FEV1/FVC and FEV1/FEV6 post bronchodilator values.

Conclusions: FEV1/FEV6 ratio is an acceptable alternative to FEV1/FVC ratio in the diagnosis of COPD in patients aged 40 years and above and with risk factors for COPD.

Keywords: COPD, FEV1/FEV6 ratio, Risk factors

INTRODUCTION

Chronic pulmonary obstructive disease (COPD) is known to mankind since long. After industrial revolution in Europe, COPD became a major cause of morbidity and mortality. Increased urbanization and industrialization has been known to precipitate COPD. But it has not been properly studied. People belonging to low social class experience more morbidity.¹

According to an international consensus statement sponsored by the ATS and ERS, COPD is defined as follows.² “Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease state characterized by airflow limitation that is not fully reversible, the airflow limitation is usually progressive and is associated with an abnormal inflammatory response of the lungs to noxious particles or gases, primarily caused by cigarette smoking. Although COPD affects the lungs, it also produces significant systemic consequences.”²

Globally COPD occurs. But it is a health hazard among those who smoke. The life expectancy is also reduced to a large extent. Hence early diagnosis may help prevent further progression of disease and motivate people to
modify their lifestyle, COPD can even be seen among non-smokers also. Every year globally COPD is responsible for three million deaths or more. Thus, it ranks the fourth leading cause of death all around the world.3

Now the estimates say that it can become third leading cause of death all around the world by 2030. As per World Health Organization, in the South-East Asia region COPD is responsible for more morbidity and mortality than compared to other disease. As per the estimates, in coming next twenty years, COPD deaths can increase by more than 160%.4

In India, there is lack of data on COPD incidence and prevalence. Only few minor surveys were conducted. The estimates for India on prevalence of COPD are 2-22% among males and a slightly lesser of 1.2-19% among females.6,8

Hence present has been carried out to know the efficacy of FEV1/FEV6 ratio in diagnosing a case of COPD in comparison with FEV1/FVC ratio and to demonstrate its utility as an alternative to FEV1/FVC ratio in the diagnosis of COPD.

**METHODS**

Two hundred and twenty-nine spirometric examinations of patients attending to pulmonary medicine outpatient department and in-patients of the Mamata General Hospital were considered for the study which fulfilled the acceptability and reproducibility criteria for spirometric examination laid down by ATS/ERS. The study was carried out between July 2010 and July 2012 among patients aged 40 years and above with symptoms suggestive of COPD with following inclusion and exclusion criteria.

**Inclusion criteria**

- Symptoms suggestive of COPD like: Cough, expectoration, shortness of breath, wheeze in elderly smokers (≥40 years)
- Patients with such symptoms performing spirometric examination in accordance with ATS/ERS criteria.

**Exclusion criteria**

- Patients with acute exacerbation of COPD and COPD with complications like cor-pulmonale and pneumothorax
- Patients with coexisting cardiac failure or congenital heart disease
- Any other significant medical/surgical illness. e.g. narrow angle glaucoma, prostatic disease, bladder outlet obstruction
- Patients with history of abdominal/thoracic surgery in past 3 months
- Chest radiograph showing any parenchymal scars, cavity, mass or any opacity.

A detailed clinical history including age, occupation, educational status, smoking history including age at onset of smoking, family history, socio-economic status, symptoms with special reference to cough, shortness of breath, wheezing, with previous work-up, and coexisting illness particularly cardiac were recorded. History of emergency visits in the past two years was also recorded.

A thorough general and systemic examination was carried out as per the working proforma. Following laboratory investigations were performed on each patient: Hemoglobin (Sahli’s method), Total leucocyte count, Differential leucocyte count, Erythrocyte sedimentation rate, Plasma glucose (glucose oxidase peroxidase method), Blood urea, Urine examination, Uristix for albumin, Microscopic examination Sugar, chest radiograph (PA and lateral views), ECG, Echocardiogram in selected cases, CT Thorax in selected cases, Spirometry (both baseline and post bronchodilator : 15 min after 400 mcg of salbutamol administration through metered dose inhaler using spacer)

**Anthropometric measurements**

**Measurement of height**

Height was measured in centimeters without shoes in standing position, heels together, heels, calf, buttocks and back touching the stadiometer. Observer cupped the mandible in his two hands, tilted the subjects so that the lower orbital margin was at the level with the external auditory meatus and applied gentle traction upward to the head.

**Measurement of weight**

By weighing machine in kilograms without shoes and with light clothing.

**Spirometer used**

Micro Lab [Micro Medical Ltd., U.K.]

An informed consent was taken from all the participants and the study was approved by the Institutional Ethics Committee. Patients aged 40 years and above, attending to pulmonology out-patient department and in-patients of Mamata General Hospital, with symptoms suggestive of COPD were subjected to spirometric examinations following standard protocol of test performance as laid down by ATS/ERS. After thorough examination of the spirometric reports of the patients, those of 229 patients were considered for the study which fulfilled the acceptability and reproducibility criteria of test performance. Such spirometric examinations were analyzed statistically to know the performance of FEV1/FEV6 ratio using a cut-off value of < 0.70 (post
bronchodilator) arbitrarily as against FEV1/FVC ratio of < 0.70 (post bronchodilator) in accordance with GOLD guidelines for the diagnosis of COPD.

**Statistical methods**

Data were expressed using mean SD for continuous variables. The paired t-test was used to compare means. The performance of the separate sets of variables was analyzed using two-by-two tables. Sensitivity and specificity were calculated and compared using a fixed cut-off point of FEV1/FVC < 0.70 as reference for airways obstruction. The level of significance was set at P < 0.05. Analyses were carried out using the SPSS (V 19) program.

**RESULTS**

The study was conducted in the Department of Pulmonary Medicine, Mamata Medical College and General Hospital, Khammam. Spirometric studies of 229 patients were included in the study which fulfilled the acceptability and repeatability criteria of test protocol, laid down by ATS/ERS.

**Table 1: Sex wise distribution of study subjects.**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>192</td>
<td>83.8</td>
</tr>
<tr>
<td>Female</td>
<td>037</td>
<td>16.2</td>
</tr>
<tr>
<td>Total</td>
<td>229</td>
<td>100</td>
</tr>
</tbody>
</table>

The study group comprised of 229 patients, of whom 192 (83.8%) were males and 37 (16.2%) were females.

**Table 2: Incidence of COPD among the study subjects.**

<table>
<thead>
<tr>
<th>Diagnostic method used</th>
<th>Incidence of COPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1/FVC ratio of &lt; 0.70</td>
<td>197 (86.03%)</td>
</tr>
<tr>
<td>FEV1/FEV6 ratio of &lt; 0.70</td>
<td>180 (78.60%)</td>
</tr>
<tr>
<td>Total</td>
<td>229 (100%)</td>
</tr>
</tbody>
</table>

Among 229 patients 197 (86.03%) were diagnosed as having COPD based on a post bronchodilator FEV1/FVC ratio of < 0.70 whereas 180 (78.60%) patients could be diagnosed based on FEV1/FEV6 ratio of < 0.70.

**Table 3: Sex wise incidence of COPD among the study subjects.**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Diagnostic method used</th>
<th>Incidence of COPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>FEV1/FVC ratio of &lt; 0.70</td>
<td>170 (88.5%)</td>
</tr>
<tr>
<td></td>
<td>FEV1/FEV6 ratio of &lt; 0.70</td>
<td>153 (79.7%)</td>
</tr>
<tr>
<td>Females</td>
<td>FEV1/FVC ratio of &lt; 0.70</td>
<td>27 (72.9%)</td>
</tr>
<tr>
<td></td>
<td>FEV1/FEV6 ratio of &lt; 0.70</td>
<td>27 (72.9%)</td>
</tr>
</tbody>
</table>

Among 192 male patients, 170 were diagnosed as having COPD based on a post bronchodilator FEV1/FVC ratio of <0.70 as against 153 based on a post bronchodilator FEV1/FEV6 ratio of <0.70. Among 37 female patients 27 were found to have COPD based on both FEV1/FVC and FEV1/FEV6 post bronchodilator values.

**Table 4: The characteristics of the study group.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>59.0±9.62</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>163.0±5.85</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>49.4±8.95</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>18.5±2.93</td>
</tr>
<tr>
<td>FEV1(L)</td>
<td>1.2±0.46</td>
</tr>
<tr>
<td>FEV6(L)</td>
<td>2.2±0.59</td>
</tr>
<tr>
<td>FVC(L)</td>
<td>2.3±0.61</td>
</tr>
<tr>
<td>FEV1/FVC</td>
<td>51.9±11.5</td>
</tr>
<tr>
<td>FEV1/FEV6</td>
<td>55.8±10.74</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Globally chronic obstructive pulmonary disease (COPD) leads to increased morbidity, disability and mortality. Overall prevalence is increasing. Thus, it is an important public health problem. It has been estimated that COPD can become 3rd most common cause of mortality in coming years.

Surveys using questionnaire method usually end in estimating a low prevalence of COPD. For true prevalence, it is important that the surveyor must use the spirometry method. Spirometry method will give objective assessment of the disease burden in the community. People also get satisfied and believe more on the diagnosis. Thus, they get naturally motivated to avoid risk factors of COPD like smoking, or exposure to...
passive smoking as well as prevent exposure to indoor air pollution.12

The most commonly used tool for respiratory function test is spirometry. It gives good results especially among old aged and middle-aged persons. In airway obstruction, there is decreased FEV1/FVC. It is difficult to perform FVC among old aged people. Bellia et al observed that the reliability of FVC recording was less than sixty percent.13 Glindmeyer et al suggested an end-of-test criterion based on a fixed duration for the FVC maneuver.14 It has been noted that for obtaining FVC result to the extent of 99%, the time required was 6.64 s. In all the tests conducted, more than 80% showed that FEV6 was obtained. FEV6 was found to be better and more reproducible than FVC. The factors like sex, and low level of education affect the repeatability of FVC as well as FEV6.

In old aged persons, for identification of COPD, FEV6 is a better option than FVC. Because spirometry is easy to carry out, it can be repeated, patient compliance is better as well as the diagnostic accuracy is better. In primary health care settings, use of FEV1/FEV6 rather than FEV1/FVC is better, because spirometry can be used in field conditions. This will help in early diagnosis and treatment. The high-risk population for COPD consists of elderly smokers, and persons with symptoms of respiratory disease. There are many advantages when we use FEV6.15 It is easy to use and reproducibility is more.16

Fixed cut off values should not be used as it can underestimate the prevalence and there are chances of misclassification. This is especially true for geriatric population.17 Hence, LLN values should be used instead of fixed cut off values. This will reduce the chances of misclassification.18,19 However, we used fixed cut-off values in our study, in view of non-availability of LLN values for FEV1/FEV6 in Indian population.

It can be observed from various studies where the best cut-off value for FEV1/FEV6 corresponding to FEV1/FVC < 0.70 was obtained, that, increasing the cut-off for FEV1/FEV6 from 0.70 may optimize its diagnostic performance further.15,16

The present study showed very satisfactory figures of FEV1/FEV6 sensitivity, specificity in the diagnosis of COPD with an arbitrary cut-off value of < 0.70 for FEV1/FEV6 compared with FEV1/FVC. In statistical analysis of the study data, Pearson correlation was highly significant (r=0.986) with a p value of <0.000 and the relationship was positively linear. Paired t-test was significant with a p value of <0.000 at 228 df (degree of freedom) which means that the FEV1/FEV6 appears to be an acceptable alternative to FEV1/FVC. Statistical analysis showed a kappa value of 0.74 which indicates substantial agreement between the two parameters.

In this study FEV1/FEV6 showed a sensitivity of 91.37%, specificity of 100%. Our study results correlate well with many of the previous studies with regard to sensitivity and specificity values.16,22,23

CONCLUSION

It can be concluded from the study that FEV1/FEV6 ratio is an acceptable alternative to FEV1/FVC ratio in the diagnosis of COPD in patients aged 40 years and above and with risk factors for COPD. The overall performance of FEV1/FEV6 ratio is good with acceptable levels of sensitivity and specificity and with positive correlation in comparison with FEV1/FVC. Since our sample is relatively small and comprises of a very high proportion (86%) of subjects with airway obstruction, the results may not be applicable for use in general population.

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Ethical approval: The study was approved by the institutional ethics committee

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