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ORIGINAL RESEARCH

CLINICAL STUDY OF PULMONARY FUNCTION TESTS IN PATIENTS OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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ABSTRACT

Background: The hallmark of COPD is airflow obstruction which is typically described by spirometry. Spirometry is a cost efficient method of ordering pulmonary function tests is to start with spirometry and then order further tests in a stepwise fashion to refine the diagnosis. Present study was aimed to study pulmonary function tests in patients of chronic obstructive pulmonary disease.

Material and Methods: Present study was Cross-sectional Observational Study, conducted in patients clinically diagnosed as COPD in OPD or admitted to our wards and having symptoms of COPD (dyspnea, chronic cough or sputum production).

Results: 100 COPD patients were studied, majority were from age group 50 to 59 years (41%) & age group 60 to 69 years (30%). The male to female ratio was 5.67:1. Mean post-bronchodilator FEV_1 % predicted of males in the group was 53.81 ± 19.29) whereas mean FEV_1 % predicted of females in the group was 51.26 ± 15.96. Mean post-bronchodilator FEV_1/FVC ratio of males in the group was 0.433 ± 0.156 whereas mean FEV_1/FVC ratio of females in the group was 0.411 ± 0.128. 15 patients were in GOLD Stage I (FEV1 ≥ 80% predicted) ,34 patients were in Stage II (50% ≤ FEV1 < 80 % predicted),36 patients were in stage III (30% ≤ FEV1 < 50 % predicted) whereas 15 patients were in stage IV(FEV1 < 30%). The difference between mean post-bronchodilator reversibility in FEV1 (in percentage) in patients in GOLD stage 1 vs stage 2 vs stage 3 vs stage 4 (applying ANOVA) was not found to be statistically significant (P=.869>0.05).

Conclusion: Spirometry is important tool in confirming and assessing severity of airway obstruction in COPD patients. Majority of COPD patients were in stage 2 & 3 (GOLD) of airway obstruction confirmed by spirometry.

Keywords: COPD, Spirometry, airway obstruction, bronchodilator.

INTRODUCTION

Chronic Obstructive Pulmonary disease (COPD) is a clinical diagnosis that should be based on careful history taking, the presence of symptoms and assessment of airway obstruction (also called airflow limitation). Worldwide, COPD affects 329 million people or nearly 5% of the population. In 2011, it ranked as the fourth leading cause of death, killing over 3 million people.[1] The number of deaths is projected to increase due to higher smoking rates and an ageing population in many countries.[2]

The hallmark of COPD is airflow obstruction which is typically described by spirometry. The GOLD international COPD guidelines,[3] as well as national guidelines,[4] advise spirometry as the gold standard for accurate and repeatable measurement of lung function. Key parameters obtained from spirometry include FEV_1 and the total volume of air exhaled during the entire spirometer maneuver [forced vital capacity (FVC)]. In patients of COPD, pulmonary function testing shows airflow obstruction with a reduction in FEV_1 and FEV_1/FVC.[5,6]

In the outpatient setting, in which several days to weeks are available to make the diagnosis, a cost efficient method of ordering pulmonary function tests is to start with spirometry and then order further tests in a stepwise fashion to refine the diagnosis.[7] Present study was aimed to study pulmonary function tests in patients of chronic obstructive pulmonary disease.

MATERIAL AND METHODS

Present study was Cross-sectional Observational Study, conducted in Department of General Medicine, D.Y. Patil Medical College, Hospital & Research Institute, Kolhapur, India. Study duration was of 2 years (July 2013 to June 2015). Study was approved by institutional ethical committee.

Inclusion criteria

- Patients clinically diagnosed as COPD in OPD or admitted to our wards and having symptoms of COPD (dyspnea, chronic cough or sputum production).

Exclusion criteria

- Patients who were suffering from tuberculosis (acid fast bacilli smear positive or negative). Bronchiectasis, pneumonia, hemoptysis, pneumothorax, lung cancer, interstitial lung diseases, occupational lung diseases.
- Patients with Respiratory failure, severe cardiovascular disease or clinically unstable.
- Patients who had recent history of eye surgery, retinal detachment, or myocardial infarction within 1 month
- Patients who after performing spirometry:- showed post bronchodilator FEV1/FVC less than 0.7 and significant reversibility (improvement of 12% and 200 ml of FEV1)/ showed restrictive pattern on spirometry (FVC below 80% predicted, FEV1/FVC ratio normal - above 0.7).
- Patients not willing to participate

An informed consent was obtained from each patient before inclusion in the study. Detailed history of all patients was taken that included severity of symptoms, duration of illness,

detailed smoking status, and exposure to domestic fuels and occupational history. Past history was also taken thoroughly to exclude past history of tuberculosis or lung cancer along with history of co-morbidities like diabetes and hypertension. Clinical examination with examination of respiratory system & Chest X-ray PA view was done in all patients. Routine blood investigations were done. Those patients who were already on bronchodilators were asked to withhold it for one day prior spirometry tests. Pre and post bronchodilator (400 µg salbutamol through metered dose inhaler) spirometry using computerised spirometer Helios 401 of all the patients was done at interval of 20 minutes after bronchodilator administration. Patients without significant reversibility were selected and their pre & post- bronchodilator FEV_1% predicted and FEV_1/FVC were observed. They were classified to pre & post-bronchodilator GOLD staging in stage 1 ($FEV_1 \geq 80\%$), stage 2 ($FEV_1 \geq 50\%$ and <80%), stage 3 (FEV1 ≥ 30 and 50%), and stage 4 ($FEV_1 < 30\%$).

Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables was tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant

RESULTS

100 COPD patients were studied, majority were from age group 50 to 59 years (41%) & age group 60 to 69 years (30%). In our study total number of male patients was 85(85%) & females were 15(15%). The male to female ratio was 5.67:1. In our study 32 patients had hypertension, 27 patients had diabetes. Out of these, 15 patients had both hypertension and diabetes. 3 patients had congestive cardiac failure. In our study out of total 85 males, 82 had history of smoking were as all 15 females were nonsmokers.

Table 1: Age Wise Distribution of Patients.

Age (Years)	Frequency (n)	Percentage (%)
30-39	1	1
40-49	18	18
50-59	41	41
60-69	30	30
70-79	10	10
Sex		
Male	85	85
Female	15	15
Co-morbidities		
Hypertension	32	32
Diabetes	27	27
Hypertension & Diabetes	15	15
Congestive cardiac failure	3	3
History of Smoking	82	82

Common symptoms noted were cough with expectoration (100 %), breathlessness (97 %), fever (20 %), swelling of feet (14 %) & pain in chest (4 %).

Table 2: Clinical Symptoms

Clinical Symptoms	No of Patients (Freq)	Percentage (%)
Cough with expectoration	100	100
Breathlessness	97	97
Fever	20	20
Swelling of feet	14	14
Pain in chest	4	4

In present study, common clinical findings were cyanosis (25 %), pallor (16 %), pedal edema (14 %), clubbing (6 %) & icterus (2 %). Respiratory Rate was < 20/min, 20-25/min & >25/min in 12 %, 55 % & 33 % cases respectively.

Table 3: Clinical findings

Signs	Number of Patients	Percentage
Cyanosis	25	25
Pallor	16	16
Pedal edema	14	14
Clubbing	6	6
Icterus	2	2
Respiratory Rate		
<20	12	12
20-25	55	55
25	33	33

Mean pre-bronchodilator FEV_1 % predicted of males in the group was 50.49 ± 18.16 whereas mean FEV_1 % predicted of females in the group was 47.93 ± 14.41, difference was not significant statistically. Mean pre-bronchodilator FEV_1/FVC ratio of males in the group was 0.408 ± 0.147 whereas mean FEV_1/FVC ratio of females in the group was 0.388 ± 0.115, difference was not significant statistically.

Mean post-bronchodilator FEV1 % predicted of males in the group was 53.81 ± 19.29 whereas mean FEV1 % predicted of females in the group was 51.26 ± 15.96, difference was not significant statistically. Mean post-bronchodilator FEV1/FVC ratio of males in the group was 0.433 ± 0.156 whereas mean FEV1/FVC ratio of females in the group was 0.411 ± 0.128, difference was not significant statistically.

Table 4: Spirometry findings

Characteristics	Male	Female	P Value
Mean Pre-bronchodilator FEV1 % Predicted	50.49 ± 18.16	47.93 ± 14.41	.606 (NS)
Mean Pre-bronchodilator FEV1/FVC Ratio	.408 ± 0.147	0.388 ± 0.115	.618 (NS)
Mean Post-bronchodilator FEV1 % Predicted	53.81 ± 19.29	51.26 ± 15.96	.630(NS)
Mean Post-bronchodilator FEV1/FVC Ratio	0.433 ± 0.156	0.411 ± 0.128	.607(NS)

Mean post-bronchodilator FEV_1 % predicted of males in the group was 53.81 ± 19.29) whereas mean FEV_1 % predicted of females in the group was 51.26 ± 15.96. Mean post-bronchodilator FEV_1/FVC ratio of males in the group was 0.433 ± 0.156 whereas mean FEV_1/FVC ratio of females in the group was 0.411 ± 0.128.

Table 5: Comparison of Pre & Post bronchodilator values

	Pre-bronchodilator	**Post-bronchodilator**	**P Value**
FEV1 % predicted	50.11 ± 17.61	53.43 ± 18.78	.199 (NS)
FEV1/FVC	0.406 ± 0.142	0.429 ± 0.152	.270 (NS)

15 patients were in GOLD Stage I (FEV1 ≥ 80% predicted) ,34 patients were in Stage II (50% ≤ FEV1 < 80 % predicted),36 patients were in stage III (30% ≤ FEV1 < 50 % predicted) whereas 15 patients were in stage IV(FEV1 < 30%). The difference between mean post-bronchodilator reversibility in FEV1 (in percentage) in patients in GOLD stage 1 vs stage 2 vs stage 3 vs stage 4 (applying ANOVA) was not found to be statistically significant (P=.869>0.05).

Table 6: Mean post-bronchodilator reversibility in FEV1 (in percentage)

Gold Stage	**Number of Patients**	**Post-bronchodilator reversibility in FEV1(in percentage)**
I: Mild	15	6.86 ± 2.66
II: Moderate	34	7.08 ± 2.78
III: Severe	36	6.52 ± 2.78
IV: Very Severe	15	6.8 ± 2.88
P Value	.869 (NS)	
Total	100	6.81 ± 2.75
P Value	.948 (NS)	

DISCUSSION

The development of COPD is slow and insidious and symptoms tend to be noted by patients only after there has been a significant loss of lung function, often to 50-60% of predicted value. COPD is markedly under-diagnosed, with recent estimates of between 25 and 50% of patients with clinically important disease being undetected or misdiagnosed. Primary care physicians are in an ideal position to be able to detect COPD in its early stages and perform spirometry to confirm the diagnosis.[8,9]

In our study maximum number of patients was in the age group 50-59 years (41%) and 60-69 years (34%). Only one patient was there in age group 30-39 years (1%). Overall maximum patients were in 6^{th} & 7^{th} decade of their lives. This indicated that prevalence of COPD is maximum in patients more than 50 years of age which was consistent with the previous literatures.[10]

In our study number of males was 85 (85%) whereas number of females was 15 (15%). Male to Female ratio was 5.67:1. In study of Mrinmoy Mitra etal,[11] all patients were males. In a

study conducted on COPD patients by S.K. Veettil etal,[12] male to female ratio was 7:1 whereas that in study conducted by Mohan etal,[13] was 7.3:1. However male to female ratio in study conducted by N.K. Jain etal,[14] was 2.36:1. Our study only confirmed the findings of these previous studies conducted that males accounted for the majority of the disease burden.

In our study 82 out of 85 males had history of smoking either bidis or cigarettes. None of the females were smokers however history of exposure to domestic fuels were present in all the females. Almost similar findings were there in a study conducted by Mohan A etal,[13] were all the males were smokers whereas none of the females smoked. Smoking continues to be an important risk factor in the development of COPD among males in the developing countries.[15]

In a study conducted by N.K. Jain etal,[14] on COPD patients mean post- bronchodilator FEV_1% predicted of the patients was 46.93 ± 14.32). Mean post-bronchodilator FEV_1 % predicted of males in the study was 48.42 ± 14.52) whereas mean post- bronchodilator FEV_1 % predicted of females in the group was 43.39 ± 13.28). Difference between mean post-bronchodilator FEV_1 % predicted of males vs females was found to be statistically significant ($P<0.001$). Mean post- bronchodilator FEV_1% predicted of the patients in the study conducted by C.R. Jenkins etal,[16] on COPD patients was 44.3 ± 13.4. The difference between findings in our study and above mentioned studies may be due smaller sample size of our study and relatively small number of females in our study. So a larger cohort study is required to find the actual difference of severity of airway obstruction in COPD between males and females.

On comparison the difference between pre & post- bronchodilator FEV_1 % predicted was not found to be statistically significant ($P=.199>0.05$). Neither the difference between pre & post-bronchodilator FEV_1/ FVC ratio was found to be statistically significant ($P=.270>0.05$). So spirometry showed that there was no significant reversibility in airway obstruction using bronchodilators. So our study using spirometry confirmed the fact that COPD characterized by airflow limitation that is not fully reversible,[17] and this non- reversibility is the hallmark of COPD confirmed by spirometry.

In our study 15 (15%) patients were in Stage 1, 34 (34%) patients were in Stage 2, 36 (36%) patients were in Stage 3 &15 (15%) patients were in Stage 4 of GOLD. Almost similar distribution of patients in different stages of GOLD was found by Mrinmoy Mitra etal,[11] in their study where maximum number of patients were in stage 2 & 3 of GOLD. Among 101 study population, 18 (17.8%) patients were in stage 1, 32 (31.7%) in stage 2, 29 (28.7%) in stage 3, and 22 (21.8%) in stage 4 of GOLD. C.R. Jenkins etal,[16] in their study found that nil patients were in GOLD stage 1, while stage 2, 3 and 4 had 35.2%, 49.4% and 15.3% of the patients respectively.

C.R. Jenkins etal,[16] in their study on COPD patients found mean post-bronchodilator reversibility in FEV_1 (in percentage) of their group was 3.7 ± 3.7 while mean post-bronchodilator reversibility in FEV_1 (in percentage) of their patients in stage 2,3 & 4 of GOLD was 4.3 ± 4.0, 3.6 ± 3.6 & 2.5 ± 3.2 respectively. However on comparison the difference between mean post-bronchodilator reversibility in FEV_1 (in percentage) in patients in GOLD stage 2 vs stage 3 vs stage 4 (applying ANOVA) was found to be statistically significant ($P=.000>0.05$) so was the case with difference between the same between whole

group vs patients in GOLD stage 2 vs stage 3 vs stage 4 (applying ANOVA) which was also statistically significant (P=.000>0.05).

So our study showed that there is no significant difference in reversibility of obstruction by bronchodilator confirmed by spirometry among patients in different stages of GOLD severity of COPD whereas above mentioned study showed that there is a significant difference in reversibility of obstruction by bronchodilator among patients in different stages of GOLD and reversibility by bronchodilator goes on decreasing with increasing GOLD severity staging of COPD.

Patients of COPD have definite airway obstruction which can be confirmed by spirometry and their degree of airway obstruction can be easily assessed by spirometry. Spirometry confirmed that there was no significant reversibility in airway obstruction and majority of COPD patients were in stage 2 & 3 (GOLD) of airway obstruction. It was also confirmed by spirometry that degree of airway obstruction increases with age of COPD patients. Moreover, our study was cross-sectional study and we believe longitudinal study is also required to study clinical profile of COPD patients and assess their degree of airway obstruction & reversibility using spirometry.

CONCLUSION

COPD is mostly prevalent in 5^{th} & 6^{th} decade of life. Majority of patients are males and smokers. Spirometry is important tool in confirming and assessing severity of airway obstruction in COPD patients. There is no significant reversibility by bronchodilator in airway obstruction in COPD confirmed by spirometry. Majority of COPD patients were in stage 2 & 3 (GOLD) of airway obstruction confirmed by spirometry. Severity of airway obstruction confirmed by spirometry increases with increasing age of patients.

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