ORIGINAL ARTICLE

Burden of Chronic Obstructive Pulmonary Disease and its Determinants among Patients Reporting to a Primary Health Facility in North India

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Anupam Parashar[1], Priyanka[2], Onno (CP) van Schayck[3], Malay Sarkar[4], Anmol K Gupta[5]

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Abstract

Context: Chronic obstructive pulmonary disease (COPD) is included in the World Health Organization (WHO) global action plan for the prevention and control of non-communicable diseases (NCDs) and the United Nations 2030 agenda for sustainable development. The World Health Organization is taking action to extend the diagnosis of and treatment for COPD in several ways.

Aims: (A) To determine the frequency and severity of COPD among patients attending the Outpatient Department at a Primary Health Care facility. (B) To determine the risk factors for COPD among these patients.

Settings and design: Cross-sectional study.

Materials and methods: This cross-sectional study was conducted among patients ≥40 years of age who had symptoms suggestive of COPD and/or the presence of its risk factors. The diagnosis of COPD and its severity was determined according to the Global initiative for chronic obstructive lung disease (GOLD) guidelines.

Statistical analysis used: Data were analyzed using the statistical software IBM SPSS 28.0. The odds ratio was estimated for COPD-related factors through multivariate regression analysis.

Results: 107 patients ≥40 years of age were enrolled as per GOLD guidelines, and 41 (38.3%) had spirometry-confirmed COPD. Chronic obstructive pulmonary disease was highest prevalent in the ≥70 years age group ($p = 0.02$) and higher in males ($p = 0.01$). Participants who were smokers had 12.5 times higher odds of having COPD than non-smokers. In multivariate analysis quantity of tobacco smoked in pack years was the independent risk factor for COPD. The maximum risk was associated with the quantity of tobacco smoked in ≥20 pack years (OR 36.7).

Conclusion: Guideline-directed management and availability of spirometry are essential at the primary levels of care for early recognition and treatment.

Keywords: Chronic obstructive pulmonary disease, Global initiative for chronic obstructive lung disease guidelines, Primary health care facility, Spirometry.

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Abbreviations used in this Article

COPD = Chronic obstructive pulmonary disease; CHC = Community Health Centre; DALYs = Disability adjusted life years; GATS = Global adult tobacco survey; GOLD = Global initiative for chronic obstructive lung disease; LPG = Liquefied petroleum gas; NFHS-5 = National family health survey-5; NCDs = Non-communicable diseases; OPD = Outpatients department; SOB = Shortness of breath; WHO = World Health Organization.

Introduction

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable chronic lung disease that affects both men and women worldwide. It is the third leading cause of death worldwide, causing 3.23 million deaths in 2019. In low- and middle-income countries, 90% of COPD deaths occur in those under 70 years of age.[1] The current estimates from the Global Burden of Disease study report 2019 state that low-income and middle-income countries account for 62.6% of the global burden of COPD and lung cancer.[2] With the increasing prevalence of smoking in developing countries and the aging population in developed nations, the prevalence of COPD is expected to rise over the next 40 years. By 2060, there may be more than 5.4 million deaths due to COPD and related conditions.[3] In India, the prevalence of COPD ranges between 6.5 and 7.7% in rural and up to 9.9% in urban India.[4] World Health Organization (WHO) reported that the prevalence of COPD ranges between 4 and 20% in Indian adults.[5] As of 2016, COPD is India's second largest cause

[1,2,5]Department of Community Medicine, Indira Gandhi Medical College and Hospital, Shimla, Himachal Pradesh, India

[3]Department of Family Medicine, School of Public Health and Primary Care, Maastricht University, Maastricht, the Netherlands

[4]Department of Pulmonary Medicine, Indira Gandhi Medical College and Hospital, Shimla, Himachal Pradesh, India

Corresponding Author: Anupam Parashar, Department of Community Medicine, Indira Gandhi Medical College and Hospital, Shimla, Himachal Pradesh, India, Phone: +91 9418035278, e-mail: anupamvikrant@yahoo.co.in

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of the five leading causes of mortality and morbidity.[6] Disability adjusted life years (DALYs) due to COPD increased by 36.3% from 1990 to 2016, becoming India's second leading cause of DALYs.[7,8]

India is a large country consisting of people with different sociodemographic profiles and diverse cultural practices; the risk factors are also likely to be different in different regions. Tobacco smoking, including second-hand smoke, is the primary risk factor for COPD. Besides this, indoor air pollution from using biomass fuel for cooking and heating, occupational dust, chemicals, and frequent childhood infection are other important risk factors for developing the disease. National family health survey-5 (NFHS-5) reports only fifty-nine percent of households use clean fuel for cooking in India; only 43.2% of households in rural and 89.7% in urban areas use clean fuel for cooking. Female tobacco use is 10.5% in rural and 5.5% in urban areas. Similarly, tobacco use by males is 42.7% in rural and 28.8% in urban areas.[9]

In Himachal Pradesh, according to the findings of the Indian Council of Medical Research and Public Health Foundation of India, COPD ranks second in terms of years of life lost; moreover, it constitutes 7.7% of the total disease burden due to non-communicable diseases (NCDs).[6] About 90% of the population in Himachal Pradesh resides in rural areas with a high prevalence of smoking and biomass usage. Global adult tobacco survey (GATS) has reported the prevalence of smoking tobacco in Himachal Pradesh as 14.2%.[10] Due to cold terrain, biomass is used as fuel not only for cooking but also for heating purposes. NFHS-5 data for the state has documented that in a rural area, 44.5% of households use clean fuel for cooking, while 94.7% of urban households use clean fuel for cooking.[11]

Primary healthcare physicians are essential in detecting and managing COPD as they manage most patients in the early stages. Unfortunately, COPD is often misdiagnosed and under-assessed in clinical practice. A failure to appreciate the disease severity and the onset of the respiratory disability is common because of the poor availability of spirometry assessment of lung functions.[12] The patient should be subjected to post-bronchodilator Spirometry according to Global Initiative of Lung Disease (GOLD guidelines) for confirmation of the diagnosis of COPD and its further management, but a guideline-directed strategy is rarely adopted.[13]

Hence, this study was planned to determine the frequency, severity, and risk factors associated with COPD using spirometry for diagnosis and staging of severity of COPD among the patients reporting to the Outpatient Department of a Primary Health Care Facility Community Health Centre, Mashobra District Shimla, Himachal Pradesh.

Materials and Methods

Study Design and Setting

This cross-sectional study was conducted among patients ≥40 years of age who had symptoms suggestive of COPD and/or the presence of its risk factors attending Outpatients Department (OPD) at a Primary Health Care Facility Community Health Centre (CHC) Mashobra district Shimla from January 1, 2020, to December 31, 2020. This CHC caters to a total population of 1,54,000 covering 70 panchayats within a radius of 20 kilometers. A panchayat consists of a village or a group of villages governed by the local elected body.

Sample Size

The sample size was calculated, assuming the prevalence of COPD to be 7%.[4] By using the formula; Sample size n = [Np (1–p)]/[(d2/Z21–α/2 (N–1) + p (1–p)] where N is the desired sample size, Z is the standard estimate = 1.96, p = prevalence of COPD, and d is the precision of the study = 5%. The sample size was estimated to be 101. https://www.openepi.com/SampleSize/SSPropor.htm.

Data Collection

The global initiative for obstructive lung disease (GOLD) guidelines were used for the diagnosis of COPD.[13] Burden of obstructive lung disease initiative (BOLD) core questionnaire and biomass questionnaire were used for data collection.[14] A face-to-face interview was conducted to fill out the BOLD questionnaire. The BOLD Committee has already permitted the utilization of the BOLD questionnaires. To define the patients' tobacco use status, we used the global adult tobacco survey (GATS) 2017 (Operational definitions in supplementary file).[10]

Spirometry

Spirolab (Medical International Research) spirometer was used for spirometry. Diagnosis of COPD was confirmed by post-bronchodilator spirometry, which is performed 15 min after administration of two doses of salbutamol sulfate (200 µg per dose). Participants were asked to refrain from using their bronchodilator during the 6–24 hours before testing. At least three best measurements were recorded for each lung function variable, and the best measurement was accepted for final analysis.

Diagnosis of COPD

Grading of COPD was done as per the GOLD criteria (Guidelines in Supplementary File).

A pulmonary medicine specialist from the tertiary care institution, visited CHC Mashobra once a month to evaluate the participants, establish COPD diagnosis, and suggest further management.

Statistical Analysis

Data was analyzed using standard statistical techniques with statistical software for IBM SPSS statistics 28.0. Pearson's Chi-square or Fisher's Exact test, as applicable, was used for categorical variables. The odds ratio with 95% confidence intervals was calculated to find the strength of the association between exposure and outcome variables. All those variables found to be statistically significant on univariate analysis at a level $p < 0.2$ were included in the final model. A forward stepwise logistic regression method was used for Multiple regression analysis. A p-value of ≤ 0.05 in statistical tests was considered statistically significant.

Results

Seven hundred and eight patients presented to the OPD during the study duration with respiratory symptoms. A total of 107 (15.1%) patients ≥40 years of age were enrolled in the study based on symptoms and/or risk factors as laid down in GOLD guidelines among patients attending OPD (Fig. 1).

Baseline Characteristics of the Study Participants

The mean age of the study participants was 64.7 ± 12.2 years with a range of 40–90 years. Among the study participants, 62 (58%) were male and two-thirds were literate. Taking cut off range for the BMI from WHO Southeast Asian population, 51.4% of the study participants were overweight and obese whereas 47.7% had normal BMI.[15]

Risk Factors

It was found that there were 56 smokers (52%) among the study participants which constituted 72% of male participants (45/62)

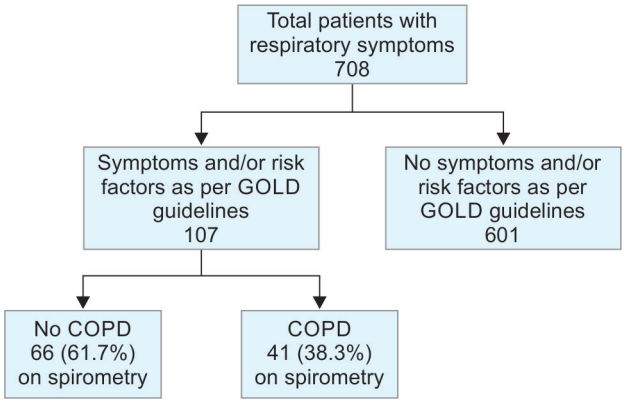

Fig. 1: Flow diagram COPD diagnosis

and 25% (11/45) of female participants. The mean age of smoking initiation was 17.5 ± 3.1 years among males and 15.5 ± 2.4 years in females. A most common type of smoked tobacco was in the form of Beedi in both sexes. Among smoking males, 40% (18/45) of the participants were current smokers while 54.6% (6/11) of the smoking females were currently smoking tobacco and the rest were ex-smokers. Two-third of males and more than half of the females were exposed to >20 pack years of tobacco smoke. 90.6% of the participants were exposed to biomass in their lifetime. More than half (56.1%) of participants had having biomass index of ≥50, and only 20 (18.7%) had a biomass index of ≥100. Most of the study participants (62.6%) had installed chimneys in their kitchen. It was found that 74.7% of the study population had exposure to dusty jobs for more than one year and 29.9% of the participants were exposed to second hand smoke at home.

Clinical Characteristics of the Study Participants

Out of a total of 107 patients who had symptoms and/or risk factors suggestive of COPD, 41 (38.3%) patients had COPD confirmed with spirometry.

Chronic phlegm production ($p < 0.001$) and shortness of breath (SOB) ($p = 0.03$) were found to be statistically significant symptoms present in COPD patients. Rest all other symptoms like chronic cough (41.5%) and exacerbation (46.4%) seemed to be more frequent among COPD patients; however, the difference was not found to be statistically significant (Table 1).

It was observed that half (50.4%) of the participants had comorbidities at the time of enrolment. Hypertension was found to be the most common (42.9%) type of comorbidity present among study participants, followed by diabetes mellitus and heart disease in 10.3% each.

Around 21.5% (23/107) of the participants knew they had chronic bronchitis, and 16/41 (39%) of COPD patients were aware that they had COPD. Only 29% (31/107) of study participants had spirometry done earlier, but no records were available for the same. Out of 41 COPD patients, only 17 (41%) had spirometry done in the past. 57% (61/107) were currently on medication for their breathing problems (including nasal congestion) which constituted 24 COPD patients (58%) and 37 (56%) non-COPD patients.

Association of Various Risk Factors with COPD

Chronic obstructive pulmonary disease was most prevalent in the ≥70 years age group ($p = 0.02$) and higher in males ($p = 0.01$).

Table 1: Distribution of clinical characteristics of patients

Symptoms	*COPD n = 41 (%)*	*No. COPD n = 66 (%)*	*p-value*
Chronic cough			
Present	23 (56.1)	28 (42.4)	0.1
Not present	18 (43.9)	36 (57.6)	
Chronic phlegm			
Present	17 (41.5)	6 (9.0)	**<0.001**
Not present	24 (58.5)	60 (91.0)	
Wheezing episodes in past 12 months			
Yes	9 (21.9)	14 (21.2)	
No	32 (78.1)	52 (78.8)	0.9
Shortness of breath			
Yes	35 (85.4)	44 (66.8)	**0.03**
No	6 (14.6)	22 (33.2)	
Exacerbation			
Yes	19 (46.4)	20 (30.3)	0.09
No	22 (53.6)	46 (69.7)	
Presence of comorbidities			
Present	21 (51.2)	33 (50.0)	0.9
Not present	20 (48.8)	33 (50.0)	
Ever taken treatment for tuberculosis			
Yes	1 (2.4)	4 (6.1)	0.3
No	40 (97.6)	62 (93.9)	

Operational definitions can be found in the supplementary files published on the journal website

The COPD group consisted of 46.3% ex-smokers and 39.0% current smokers. It was found that the proportion of COPD was significantly higher in current smokers and in those exposed to more pack years of tobacco smoke ($p < 0.05$). Other risk factors like exposure to dusty jobs and second hand smoke had no significant association with COPD prevalence.

In this study, the odds of having COPD were significantly associated with advancing age, gender, tobacco smokers, exposure to ≥20 pack years of tobacco smoke, and exposure to a biomass index of ≥60. Participants who were smokers had 12.5 times higher odds of having COPD than non-smokers. Similarly, the odds of having COPD were higher (29.9 CI: 10.2–88.0) among those who smoked ≥20 pack years of tobacco (Table 2).

On multivariate analysis, the quantity of tobacco smoked in pack years was found to be the independent risk factor for COPD. The maximum risk was associated with the quantity of tobacco smoked in ≥20 pack years (OR 36.7) (Table 3).

Distribution of Participants according to GOLD Classification

According to the GOLD classification, 29% had mild to moderate COPD, 7% had severe COPD (Grade III) and only 2.8% of the participants had very severe COPD (Grade IV) (Fig. 2). There was no significant difference in clinical characteristics among different COPD stages.

Table 2: Association of various risk factors with COPD

Risk factors	*Odds ratio*	*95% CI*	*p-value*
Age in years			
≥60	2.4	1.01–5.9	**0.04**
<60	Reference		
Gender			
Male	2.8	1.2–6.7	**0.01**
Female	Reference		
Socioeconomic status			
Middle, lower middle and lower	2.0	09–4.7	0.1
Upper and upper middle	Reference		
Education status			
Up to matriculation	2.2	0.58–8.7	0.2
Above matric	Reference		
Smoking status			
Smoker	12.5	4.5–34.2	**<0.001**
Non-smoker	Reference		
Quantity of tobacco smoked (Pack years)			
≥20	29.9	10.2–88.0	**<0.001**
<20	Reference		
Biomass index			
≥60	2.7	1.2–6.4	**0.01**
<60	Reference		
Dusty jobs more than one year			
Yes	1.3	0.53–3.3	0.5
No	Reference		
Second hand smoke			
Yes	0.7	0.3–1.8	0.3
No	Reference		

Operational definitions can be found in the supplementary files published on the journal website

Table 3: Association of COPD with risk factors on multivariate analysis

Risk factors	*Unadjusted odds ratio*	*Adjusted odds ratio (95% CI)*	*p-value*
Age in years			
≥60	2.4	1.3 (0.3–4.8)	0.7
<60	Reference	Reference	
Gender			
Male	2.8	0.7 (0.2–2.8)	0.6
Female	Reference	Reference	
Smoking status			
Smoker	12.5	1.7 (0.4–7.8)	0.5
Non-smoker	Reference	Reference	
Pack years			
≥20	29.9	36.7 (7.4–182.1)	<0.001
<20	Reference	Reference	
Biomass index			
≥60	2.7	2.6 (0.8–9.1)	0.1
<60	Reference	Reference	

Only factors statistically significant in univariate analysis at a level $p < 0.2$ are included in the multivariate analysis model

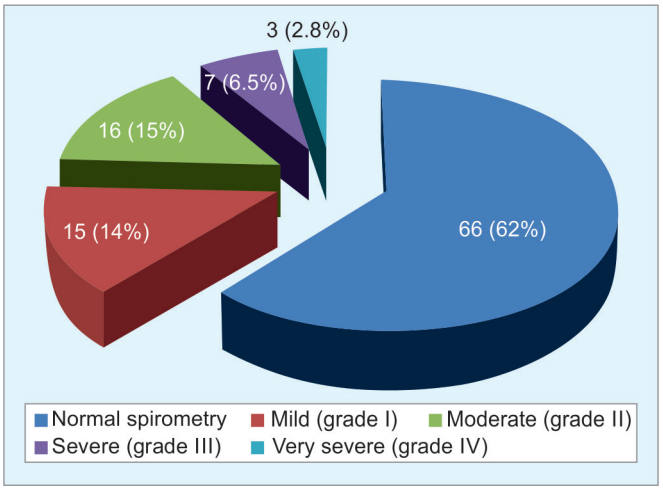

Fig. 2: Distribution of participants according to severity of COPD as per GOLD classification

Comparison of Various Socio-demographic Variables, Risk Factors, and Clinical Characteristics of COPD Patients according to Different GOLD Stages

While comparing age groups with the severity of COPD according to GOLD classification, it was found that the increase in age ($p = 0.2$) and gender ($p = 0.1$) was not significantly associated with the severity of the disease.

As a risk factor, the smoking pattern was associated with the severity of the disease, as the Ex-smoker and the current smoker had more chances of having the severe to very severe disease than the never-smoker ($p = 0.04$). A significant difference was found between the severity of COPD and mean pack years of smoking. More mean-pack years of tobacco smoked was associated with more severe disease ($p < 0.001$) (Table 4).

Discussion

Our study found that the proportion of spirometry-confirmed COPD was 38.3% (41/107). Out of 41 COPD patients, only 17 (41%) got spirometry done in the past. About 16/41 (39%) of COPD patients were told by a healthcare provider that they had COPD. It is widely known that COPD is often misdiagnosed and under-assessed in clinical practice.[16] Under diagnosis of COPD is a global phenomenon, with 10–95% of cases of COPD remaining under-diagnosed. Underutilization of spirometry is the strongest predictor for an incorrect diagnosis of COPD.[17] An average clinician in India frequently ignores COPD as simple bronchitis or asthma. In primary care settings, due to the non-availability of spirometry assessment of lung functions, there is a failure to diagnose COPD.[12]

About 57% (61/107) of study participants were currently on medication for their breathing problems (including medication for nasal congestion), constituting 56% of non-COPD patients. This highlighted the phenomenon of COPD over diagnosis followed by overtreatment. It has been reiterated that the GOLD Guidelines for managing COPD are available for different levels of health care in India, but a guideline-directed strategy is rarely adopted.[12]

The proportion of spirometry-confirmed COPD was 38.3% in this study. Sandelowsky et al. reported spirometry confirmed COPD at 27%, Stafyla et al. and 17.8% in a study conducted in Greece.[16,18] In contrast to our study, Mandke et al. in Gujarat, reported a prevalence

Table 4: Distribution of smoking status and COPD GOLD classification

Smoking status	*GOLD 1 n = 15 (%)*	*GOLD 2 n = 16 (%)*	*GOLD 3 n = 7 (%)*	*GOLD 4 n = 3 (%)*	*Total n = 41*	*p-value*
Smoking pattern						
Never smoker	6 (100)	0	0	0	6	
Current smoker	4 (25)	7 (43.8)	3 (18.8)	2 (12.5)	16	**0.04**
Ex-smoker	5 (26.3)	9 (47.4)	4 (21.1)	1 (5.3)	19	
Mean pack years						
	14.3 ± 12.8	31.5 ± 9.1	35.8 ± 3.4	41 ± 4.5		**<0.001**
Biomass Index						
<50	7 (41.2)	7 (41.2)	3 (17.7)	0	17	**0.2**
50–100	3 (21.4)	5 (35.7)	3 (21.4)	3 (21.4)	14	
>100	5 (50)	4 (40)	1 (10)	0	10	

Operational definitions can be found in the supplementary files published on the journal website

of 14.1%, Sinha et al. 10.1%, and a study in Kashmir reported a prevalence of 16.1%.[19–21] The higher proportion of COPD patients in the current study (38.3%) may be due to methodological differences, as our study was done in a primary healthcare facility and was not community-based and the patients suffering from respiratory symptoms were presenting to the outpatient department for treatment of their respiratory complaints.

The proportion of COPD patients significantly increased with age ($p = 0.02$). More men had COPD than women ($p = 0.01$). Studies worldwide have also observed a male preponderance in the prevalence of COPD. A study conducted by Sandelowsky et al. in Sweden reported the prevalence of COPD among those aged 55–75 as 43% ($p < 0.001$), and men had more COPD cases.[17] Similar findings were reported by Salvi et al. in Pune, Sinha et al. in Delhi, and studies from different parts of the world.[2,20,22–24] High prevalence in a male could be due to different lifestyles and genetic predispositions, but more likely due to smoking habits, which are more common in males.

We observed that COPD cases increased with the increase in biomass exposure though the difference was insignificant. However, a study by Mahesh et al. found a positive correlation between biomass exposure and the development of chronic bronchitis in Pune.[25] This difference could be because of the selection of study participants, as this study was conducted among women only and the majority of our study population was male. Aggarwal N et al. in Haryana also reported a significant association between biomass exposure and COPD ($p = 0.04$).[26] The reason for this may be that people residing in this particular area were using biomass generally in winter seasons only. Liquefied petroleum gas (LPG) is usually used for cooking in summer. So the exposure to biomass cannot be precisely quantified. Moreover, it was not a continuous exposure. In our study, it was found that exposure to dusty jobs ($p = 0.5$) and exposure to second hand smoke were not significantly associated with the development of COPD ($p > 0.5$) as also reported by Aggarwal N et al.[26]

Our study revealed that current smokers and ex-smokers had more chances of developing severe disease than non-smokers ($p = 0.04$). We also found a significant association in terms of pack years of tobacco smoking with the severity of COPD ($p = 0.008$). It was also observed that the mean pack-years of smoking were different among varied stages of COPD and had a significant association with the severe form of COPD ($p < 0.001$). Our findings concord with the study conducted by Mrinmoy et al. and Pandolfi et al., where they found that the mean pack year of smoking increased with the severity of the disease.[27,28] However, Soni and Jain in Maharashtra found no association with the quantity of tobacco smoked.[29]

Risk factors, i.e., advancing age, male sex, exposure to biomass, and exposure to dusty jobs, were not significantly related to the severity of COPD. These findings aligned with the results of Pandolfi et al. and Soni NA and Jain.[28,29] On univariate analysis, it was found that age ≥60 years (OR 2.4 CI 1.01–5.9), male gender (2.8 CI 1.2–6.7), smoking status (12.5 CI 4.5–34.2), ≥20 pack years tobacco smoked (29.9 CI 10.2–88.0) by participants and biomass index ≥60 (2.7 CI 1.2–6.4) were having higher odds of developing COPD. Similar findings were observed by Sinha et al.[20] On multivariate analysis; it was observed that intensity of smoking ≥20 pack years of tobacco is independently associated with COPD. However, our study findings regarding age, gender, smoking status, and biomass exposure were not independently associated with the severity of COPD. Another study by Sandelowsky et al.[18] and Mejza et al.[30] reported a significant association between smoking status and the quantity of tobacco smoked with COPD.

The strength of our study is the objective criteria used for diagnosing COPD in a peripheral health facility and the availability of a pulmonary medicine specialist at the peripheral health facility to establish a COPD diagnosis.

Our study had certain limitations because we used a fixed ratio to define obstruction, such as FEV1/FVC post-bronchodilator <70%. Ideally, a lower limit of normal should be used. In addition, this study is hospital-based; the present study could not elicit the true prevalence in a random population of an important but often neglected NCD in the form of COPD.

Conclusion

Standard guidelines like GOLD guidelines may be percolated in peripheral health institutes so that all COPD patients are managed according to standards. Diagnostic facilities need to be improved in peripheral health institutes. It would be emphasized to competent health authorities in the state health department to provide spirometry firstly at district headquarters and subsequently in peripheral health institutes so that COPD could be picked up at the primary health care level. Since smoking is a significant risk factor for the development of COPD, behavior change communication activity against smoking may be an upsurge at the peripheral healthcare facility level. The prominent ranking of COPD among the four leading causes of DALYs in age groups 50 years and above also emphasizes the continuing need for tobacco-control measures.[2] Early diagnosis

of undiagnosed COPD may act as a deterrent to smoking also.[31] This will help to decrease the enormity of the burden from COPD-related morbidity and mortality and make progress toward the United Nations 2030 Agenda for Sustainable Development.

Ethical Approval

Prior permission was taken from the Institutional Ethics Committee for pursuing this study. Written informed consent was taken from each participant after explaining the purpose of the study. Every precaution was taken to respect the patient's privacy and confidentiality of the patient's information.

Supplementary Material

All the supplementary materials are available online on the website of "https://www.ijcdas.com/".

Orcid

Anupam Parashar https://orcid.org/0000-0002-6723-7972
Malay Sarkar https://orcid.org/0000-0002-2644-2750

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