

Economic burden of chronic obstructive pulmonary disease

K.J.R. MURTHY, J.G. SASTRY

Chronic obstructive pulmonary disease (COPD) refers to a group of disorders characterized by chronic airflow obstruction/limitation. The airway obstruction is persistent and largely irreversible. It includes two distinct pathophysiological processes—chronic bronchitis and emphysema. It is associated with an abnormal inflammatory response of the lungs to noxious particles or gases, especially tobacco smoke and air pollution—both indoor and outdoor.

Chronic bronchitis manifests as chronic cough and sputum production for more than 3 months in a year for at least 2 consecutive years. Exacerbations are frequent, more so during winter, resulting in progressive loss of the functional capacity of the lungs. It is of great public health importance, because it is largely preventable if identified in the early stages and treated properly. In the initial stages, no abnormal signs are seen. Most often, COPD is interpreted as smoker's cough with little or no breathlessness. If not detected and attended to with proper medication, deterioration slowly sets in as it progresses into the moderate form with breathlessness and/or wheezing on moderate exertion. Most importantly, the patient's inability to exert results in reduced ability to work and loss of wages. The patient not only suffers from physical discomfort but also undergoes medical treatment resulting in financial and psychological distress. The disease is gradually progressive with each episode of exacerbation leading to further respiratory disability and, ultimately, death.

COPD is currently the fourth leading cause of death worldwide.¹ The Global Burden of Disease Study estimated that in 1990, the worldwide prevalence of COPD was 9.34 per 1000 men and 7.33 per 1000 women. As these estimates are based on the total population, and the problem is seen mostly among older adults, the true age-specific prevalence will be much higher, especially in countries where cigarette smoking is common.

This paper attempts to quantify the magnitude of COPD and its economic implications for society.

Need to study the burden of disease

The definition of health has undergone major changes during the past 50 years and concurrently all countries have realized the need for developing their nations along a pre-planned path that includes provision of basic health needs. Such a planning operation requires prioritization of needs for monetary allocation. Economists who most often manage decision-making bodies such as planning commissions would look for the burden of disease (BOD) in terms of the caseload and quantum of economic burden borne by the society. These estimates of BOD help to plan priorities and allocate funds to suit strategies to control and eliminate the disease to the extent possible. The larger the economic burden, the more will be the role of interventions by health planners/managers of the State.

Review of the literature

A review of the scientific literature on COPD from India and other countries reveals the following:

- The spectrum of clinical manifestations of COPD is wide. There are great variations in the reported morbidity, which could partly be due to differences in the definition of a 'case'.² The data on mortality also underestimate COPD as a cause of death because the disease is more likely to be cited as a contributory rather than an underlying cause of death, or may not be cited at all.³ Depending on the severity of the disease, the 5-year mortality rate for patients with COPD varies from 40% to 70%. The three major causes of death have been identified as COPD itself, lung cancer and cardiovascular disease.⁴
- The studies were confined to limited areas and do not represent the general population of that State or region. Table 1 presents the variation in prevalence rates reported by different researchers in India during 1964–1995.⁵

Mahavir Hospital and Research Centre
10/1/1, Mahavir Marg, A.C. Guards
Hyderabad 500004
e-mail: kollurijrm@hotmail.com; gjandhyala@hotmail.com

Table 1. Prevalence of COPD and its association with smoking as shown by the various population studies from India

Author/s (year)	Population	Prevalence of COPD (%)			Smoker:non-smoker ratio
		Men	Women	M:F ratio	
Wig <i>et al.</i> (1964) ⁶	Delhi (rural)	3.36	2.54	1.3	2.0
Sikand <i>et al.</i> (1966) ⁷	Delhi	7.0	4.3	1.6	2.5
Viswanathan (1966) ⁸	Patna	2.12	1.33	1.6	
Bhattacharya <i>et al.</i> (1975) ⁹	UP (rural)	6.67	4.48	1.6	
Radha <i>et al.</i> (1977) ¹⁰	New Delhi	8.1	4.6	1.8	1.8
Thiruvengadam <i>et al.</i> (1977) ¹¹	Madras (now Chennai)	1.9	1.2	1.6	10.2
Viswanathan and Singh (1977) ¹²	Delhi (rural)	4.7	3.5	1.3	9.6
	Delhi (urban)	8.0	4.3	1.9	4.0
Charan (1977) ¹³	Punjab (rural)	2.28	1.63	1.4	
Malik (1986) ¹⁴	North India (rural)	9.4	4.9	1.9	5.5
	North India (urban)	3.7	1.6	2.3	7.0
Jindal (1993) ¹⁵	North India (rural)	6.2	3.9	1.6	
	North India (urban)	4.2	1.6	2.6	9.6
Ray <i>et al.</i> (1995) ¹⁶	South India	4.08	2.55	1.6	1.6

- The prevalence of COPD is confined to adults 30 years of age and above.
- Table 2 shows that the prevalence of COPD did not change much over a period of time.
- The prevalence rates of COPD in males varied from 2.12% to 9.4% in studies conducted in north India and from 1.4% to 4.08% in south India. The respective ranges for females were 1.33%–4.9% in north India and 2.55%–2.7% in south India. The median values of these prevalence rates are 5% for males and 2.7% for females. Thus, COPD is more common among males than females. The male to female ratio varied from 1.32:1 to 2.6:1 with median ratio of 1.6:1.⁵
- A strong association exists between tobacco smoking and the occurrence of COPD. The reported smoker: non-smoker prevalence ratio varied from 1.6 to 10.2. Thus, smoking has been identified as a high-risk factor for COPD.⁵ Surveys in India have revealed that 29.4% of males and 2.5% of females are current smokers.¹⁷ However, in those 30 years of age and above, the prevalence of smoking in India is 40.9% for males and 3.9% for females. The difference in the prevalence of COPD among males and females could be due to the differences in their levels and type of smoking. Further, it is seen that the magnitude of smoking increases with age (Table 3).
- Indoor air pollution due to traditional domestic fuels was considered an important factor affecting the lung function of females in rural areas in prevalence studies of COPD.¹⁸ However, no consistent evidence was observed in this direction.
- The occurrence of severe bronchitis among non-smokers was mainly due to their exposure to tobacco smoke either at home or at the workplace.¹⁹ The prevalence of COPD was much higher in heavy smokers than among those who smoked a lesser number of cigarettes. The odds ratio was 2.4 for the total population—4.7 for

Table 2. Prevalence of COPD—changes over the years (%)

Period	Males	Females
Up to 1970	4.2	2.7
1971–1990	5.7	2.6
After 1990	4.9	2.7
Average	5.0	2.7

Table 3. Prevalence of smoking among different age groups by sex (%)

Age group (years)	Males	Females
15–19	4.4	0.2
20–24	13.7	0.6
25–29	25.1	1.1
30–39	37.6	2.2
40–49	45.0	4.0
50–59	45.3	5.7
60+	38.2	5.3
Average	29.4	2.5

Table 4. Mortality due to chronic bronchitis/100,000 British male doctors²⁰

No. of cigarettes/day	Mortality
Nil	3
1–14	51
15–24	78
≥25	114
Ex-smokers	44

Source: Doll and Peto (1976)

females and 1.5 for males.² Among British male doctors, deaths due to chronic bronchitis were found to increase directly with the number of cigarettes smoked per day (Table 4). A decrease in mortality was seen among ex-smokers. However, the mortality was much higher than

that seen among non-smokers.²⁰ Similar observations were also made in large-scale studies conducted in the USA and Canada.

- An association was seen between the method of smoking and the occurrence of chronic bronchitis. Pipe and cigar smokers were found to have a lower prevalence of the disease and less impairment of lung function even though the inhalation of cigar smoke is as irritative as that of cigarette smoke.^{21–23} Introduction of the Clean Air Act 1981 has drastically reduced the morbidity due to lung dysfunction, if not COPD. In areas with high levels of industrial pollution, the effect of enforcement of anti-pollution laws was not clearly seen because of the increase in the cigarette smoking habits of the population. In other words, the beneficial effects of control of atmospheric pollution on bronchial health are difficult to demonstrate at a macro level. However, its indirect impact on the prevalence of COPD can be expected.
- A majority of cases with chronic COPD (57.4%) were found to suffer from a mild form and only 16% had severe COPD. The remaining 26.6% formed the moderate category. In fact, 81.4% of cases from the mild category (i.e. 46.7% of the total number of cases) were not aware that they had the disease and hence did not seek any medical advice.² The remaining 18.6% of these mild cases sought treatment as outpatients.
- A large-scale study in Hyderabad city and its surrounding municipalities, covering a population of more than 54 lakh and 28 hospitals/health posts, was done in 2001 to collect cause-specific morbidity data. The rates of hospital admissions of cases with COPD showed an age differential. While the rate was 47.84/100,000 persons at the community level, it was 57.28 for those 18–64 years of age and 546.17 for those above 65 years of age.²⁴ Similar differences among the various age groups have been reported earlier.¹²
- The unit values of hospital admission for COPD were US\$ 122.23 towards medical costs and US\$ 14.30 for opportunity loss; outpatient visits cost the patients US\$ 8.26 for medicines and another US\$ 1.43 because of opportunity losses. These costs (reported for the year 2001) were used to arrive at the current cost of COPD.²⁴
- It was noted that, on an average, a person with COPD spent Rs 11,952 per year in 1992 and the same treatment cost Rs 23,300 in 1999.²⁵ This increment in the cost of treatment was calculated on a pro rata basis for the period 1996–2016. In the present exercise, the same rate of change was applied for all other costs.

Data used for the present exercise

The number of cases with chronic and severe COPD was estimated by using the projected population figures for the period 1996–2016.²⁶ The expected changes in the mortality figures in India were considered in this exercise.

Table 5. Treatment cost of a patient with COPD per year (in Rs)—current level

Year	Chronic case	Hospitalization cost (acute case)	Total cost
1991	10,331	2,390	12,721
1996	18,436	4,167	22,603
2001	26,541	6,144	32,685
2006	34,646	8,018	42,664
2011	42,751	9,894	52,645
2016	50,856	11,774	62,630

Only the population of those 30 years of age and above was considered, and a constant percentage (26.82%) for the urban population was operated till 2016.

To calculate the economic cost of COPD, the following factors were taken into account:

- A conversion factor of US\$ 1 = Rs 45 was applied to costs that were provided in dollars. Table 5 gives information on the economic costs (in Rs) in one year for each patient with COPD.^{12,25}
- Treatment guidelines for COPD were drawn up (Appendix 1) and the cost of treatment (per year) was arrived at to evaluate the potential savings that would accrue to the patient.²⁷ The cost of treatment (per year) adopted to arrive at the economic burden of COPD when the treatment was according to the guidelines is provided in Table 6.

The costs of medicines adopted from the guidelines' approach are based on the least expensive and effective drugs available in the market. The cost of treatment of a patient with acute COPD per year has two components—cost of regular medication and cost of hospitalization. The cost of regular medication was taken as that for a mild case and was applied to all acute cases of COPD, while the cost of hospitalization was the same as that of the current levels. As an example, the cost of Rs 4444 for the year 1996 is the sum of the cost of treatment (Rs 277) and that of hospitalization (Rs 4167). All these rates of prevalence (given per 100,000 population) and costs of treatment of COPD have been applied on the estimated number of cases among the projected population figures for the period 1996–2016.²⁶

Table 6. Treatment cost of a patient with COPD per year (in Rs)—according to Guidelines*

Year	Mild	Moderate and severe	Acute case
1996	277	913	4,444
2001	400	1320	6,544
2006	522	1723	8,540
2011	644	2126	10,538
2016	766	2529	12,540

*Guidelines given in the *Monthly Index of Medical Specialities*

Table 7. Estimated number of patients with chronic COPD (in lakh)

Year	Males		Females		Total	
	Urban	Rural	Urban	Rural	Urban	Rural
1996	23.4	63.8	11.2	31.6	34.6	95.4
2001	26.6	72.6	13.2	37.0	39.8	109.6
2006	30.2	82.3	15.1	42.6	45.3	124.9
2011	34.3	93.5	17.2	48.3	51.5	141.9
2016	39.4	107.6	19.7	55.4	59.1	163.0

Results

The estimated number of patients with chronic and acute COPD and their distribution by sex and residence are given in Tables 7 and 8.

Health providers/planners need to get ready to face a caseload of COPD of about 222.16 lakh in 2016—a majority of this would be from rural areas where the poverty levels are high.

Table 8. Estimated number of patients with acute COPD (in lakh) by sex and residence

Year	Males		Females		Total no. of acute cases		
	Urban	Rural	Urban	Rural	Urban	Rural	Total
1996	0.69	1.89	0.62	1.75	1.31	3.64	4.95
2001	0.78	2.13	0.72	2.02	1.50	4.15	5.65
2006	0.89	2.44	0.83	2.35	1.73	4.78	6.51
2011	1.03	2.82	0.97	2.72	2.00	5.54	7.54
2016	1.20	3.28	1.13	3.18	2.34	6.47	8.81

Table 9 provides information on the estimated case-load according to the severity of COPD. In addition, there would be patients with acute COPD who need hospitalization and expert care.

The current annual cost of treatment was arrived at and the results are presented in Table 10.

It is estimated that a staggering amount of more than Rs 48,000 crore will be spent by patients and their families on the treatment of COPD alone in the year 2016. The total amount of money spent by these patients can be drastically reduced by adopting a number of strategies such as controlling various contributory factors, e.g. tobacco smoking, providing hospital care at cheaper rates and marketing the medicines at lower costs. These strategies

Table 9. Estimated number of patients with COPD by severity of the disease (in lakh)

Year	Severity of COPD			Total
	Mild	Moderate	Severe	
1996	75.67	33.28	21.06	130.01
2001	86.92	38.23	24.19	149.35
2006	99.04	43.57	27.57	170.18
2011	112.52	49.49	31.32	193.33
2016	129.30	56.87	35.99	222.16

Table 10. Total cost of treatment for COPD (Rs in crore)—current level

Year	Urban	Rural	Total
1996	2,729.1	7,519.4	10,248.5
2001	4,512.5	12,435.5	16,948.0
2006	6,711.5	18,497.7	25,209.1
2011	9,408.1	25,929.6	35,337.7
2016	12,860.9	35,445.2	48,306.1

are considered to be difficult to implement. However, if all patients with COPD are treated according to the suggested guidelines, the estimated cost of treating COPD can be reduced considerably (Table 11).

The present exercise provides an opportunity to compare the current cost of COPD (Table 10) with that of the guidelines (Table 11). The difference between these two estimates of costs provides valuable information on the notional savings that accrue to patients and their families; a large number of them come from rural areas and are poor (Table 12).

Table 11. Total cost of treatment for COPD according to the guidelines* (Rs in crore)

Year	Urban	Rural	Total
1996	254.73	702.69	957.42
2001	525.41	1449.30	1974.70
2006	782.68	2159.22	2941.90
2016	1507.23	4158.10	5665.33

*Guidelines given in the *Monthly Index of Medical Specialities*

Discussion

The present exercise cannot be used to precisely estimate the economic burden of COPD in India because of inadequate information. Unlike asthma, the prevalence of COPD has not shown any change during the past 30 years. Further, there is a dearth of data on the frequency of medical consultation, hospitalization, and opportunity losses to the patient and attendants. Mortality rates among patients with COPD are not available for India. In the present exercise, the costing is mostly based on the large-scale investigation carried out in and around Hyderabad. In the absence of such data on costing from other parts of the country, the results were extrapolated for the entire country.

Table 12. Total cost of treatment of a patient with COPD (Rs in crore)

Year	Guidelines	Current cost
1996	957.42	10,248.5
2001	1974.70	16,948.0
2006	2941.90	25,209.1
2011	4135.17	35,337.7
2016	5665.33	48,306.1

The differences between the current costs and those according to guidelines were enormous. We have considered the average cost of the medicines (guidelines) that are mostly prescribed. Only a common pro rata change was applied to all costs in the present study. The cost of medicines was calculated for a calendar year, and all patients with acute COPD were assumed/expected to be admitted in a hospital once a year.

Exacerbations with increased cough, sputum and, often, wheezing are frequent in patients with chronic bronchitis and emphysema, though progressive deterioration in respiratory function occurs with very little cough or sputum and no exacerbations in some smokers. However, each infective exacerbation produces further lung damage and adds to the permanent impairment of respiratory function.

A number of studies have shown a correlation between the deterioration of respiratory function and frequency of exacerbations.²⁸ However, correlation does not necessarily imply causation. A number of confounding factors may be operating on both these variables, such as hereditary factors or living conditions congenial for acquiring different infections, as well as smoking habits. The prevalence of chronic bronchitis among the rural population was 57 per 1000 population. The type of smoking influenced the magnitude of prevalence.⁹ The prevalence of chronic bronchitis in *hookah* smokers was 85/1000 population, in *beedi* smokers 31/1000, and in *chillum* smokers 17.5/1000. It was seen that 13.5% of *beedi* smokers had chronic bronchitis.²⁹

The strong association between cigarette smoking and COPD points out the need to bring about drastic changes in the smoking habits of the population through legislation and increase in the cost of cigarettes. However, it is known that such a strategy would take 10–15 years to bring about a reduction in the prevalence rate; the higher prevalence rates seen in males as compared to females could be due to the higher levels of smoking among them. The results of the National Family Health Survey (NFHS)-2 show that around 4.5% of males in the age group of 15–19 years and about 14% of those 20–24 years of age are current smokers.¹⁷ However, most field-based studies have observed that the problem of COPD exists only in adults 30 years of age and above. Does this mean that it takes about 10–15 years for COPD to develop after the initiation of cigarette smoking? In fact, the data presented in the NFHS-2 on current smokers in India from different age groups and by sex, show the prevalence of smoking to be 40.9% among males and 3.91% among females 30 years of age and above (23.06% for both the sexes).¹⁷

Population studies have found that chronic bronchitis is almost confined to smokers. In males 55–64 years of age, the prevalence of chronic bronchitis was found to be 17.6% in heavy smokers, 13.9% in light smokers, 4.4% among ex-smokers and nil among non-smokers.^{22,30} The effect of cigarette smoking may begin at an early age, as indicated by increased respiratory illness and diminished pulmonary function in children passively exposed to cigarette smoke

at home. After adjusting for age and frequency of smoking, it was found that women who smoke heavily were more susceptible than men to acquire smoking-related COPD (odds ratio [OR]=4.7).¹⁴ Significant regional differences in the prevalence of COPD were seen in Greece.² Reports from northern India, which incidentally has cooler climatic conditions accompanied by smog during winter, also suggest that the prevalence may be higher than that in south India. The range of prevalence rates reported in males from north India (2.12%–9.4%) is generally higher than that reported from south India (1.4%–4.08%).³¹ At the all-India level, the male to female smoking ratio was seen to be 11.76:1, which strongly suggests that males should be the focus group for information, education and communication (IEC) activities. While the rural/urban coverage among males and females in the survey is comparable (males: 2.48 and females: 2.58), these ratios among smokers are 3.78 for males and 8.89 for females. This observation indicates that females cannot be ignored (more so in rural areas) for IEC activities. The ratio of males to females among current smokers is 25.44:1 in urban areas and 10.81:1 in rural areas.¹⁷ A review of the literature shows the prevalence of COPD to be around 5% among males and 2.7% among females, with a male to female ratio of 1.85:1.⁵ A ban on cigarette smoking in public places is a step in the right direction. Even if attempts are made to control the younger generation from getting into this habit, its impact will not be seen for another 10–15 years.

The impact of air pollution on the occurrence of chronic bronchitis was studied in workers from a machine tools factory and woollen hosiery mills. It was found that chronic bronchitis was mainly related to smoking, with air pollution playing a minor role.³²

The present study highlights the need to focus on the health infrastructure so that the magnitude of COPD cases in rural areas can be handled.³³ It is known that methodological differences are also responsible for differences in the prevalence rates. The assessment of severity is based on the degree of the spirometric abnormality. Based on the results of spirometry, COPD can be categorized into five stages: at risk, mild, moderate, severe and very severe (Table 13).³⁴

It is a common observation that such objective measurements to categorize a patient by the severity of the disease are not possible under field conditions, particularly in rural and tribal areas of India. Further, adoption of such techniques needs highly trained manpower to collect the information, while the operational costs of the survey increase enormously. Hence, there is a need to adopt simple criteria to define a case, which brings in the factor of trade-off between the quality of the data and cost of data collection.

More than 80% of cases with mild COPD among the Greek population were found to be ignorant of their problem and hence did not seek any medical assistance/advice.² It is most likely that a similar situation prevails in India. If we could only have peripheral health workers constantly

Table 13. Global initiative for chronic obstructive lung disease (GOLD): Classification of severity³⁴

Stage	Characteristics	Symptoms
0: At risk	<ul style="list-style-type: none"> • Normal spirometry • Chronic symptoms (cough, sputum production) 	Normal
1: Mild	<ul style="list-style-type: none"> • FEV₁/FVC <70% • FEV₁ >80% predicted • With or without chronic symptoms (cough, sputum production) 	Patient not aware of the problem
2: Moderate	<ul style="list-style-type: none"> • FEV₁/FVC <70% • 50% ≤ FEV₁ ≤ 80% predicted • With or without chronic symptoms (cough, sputum production) 	Shortness of breath on exertion. All patients seek medical attention.
3: Severe	<ul style="list-style-type: none"> • FEV₁/FVC <70% • 30% ≤ FEV₁ ≤ 50% predicted • With or without chronic symptoms (cough, sputum production) 	Increased breathlessness; quality-of-life affected because of repeated exacerbations.
4: Very severe	<ul style="list-style-type: none"> • FEV₁/FVC <70% • FEV₁ <30% predicted or FEV₁ <50% predicted + chronic respiratory failure • With or without chronic symptoms (cough, sputum production) 	Quality-of-life appreciably affected; exacerbations may be life-threatening.

Source: National Institutes of Health 2003

monitoring the situation through IEC activities, all these mild cases could have the necessary medical intervention, and avoid suffering and deterioration of their health because of exacerbations, with simple and cheap medications. In other words, it emphasizes the need for the existing health care system to identify this 'silent' cohort of patients with COPD to prevent further progression of the disease. The following issues need serious consideration:

- COPD should be considered in any patient with a history of exposure to risk factors (especially tobacco smoking) and suggestive symptoms.
- Investigations should be done for patients presenting with chronic cough and expectoration not cured with first-level drugs. The use of a nebulizer would help the patient; this facility should be made available in all primary health centres (PHCs) to start with. It is expected that other private medical practitioners would also initiate the process depending upon the local needs. The medical officer at the primary care level has to be satisfied before a request for a chest X-ray is made to exclude and/or recognize alternate diagnoses and problems. It should always be done at the secondary care level. This facility should be available in all PHCs.

- Spirometry should be attempted if there is a doubt about the diagnosis. Proper equipment should be added with adequately trained manpower and UPS for computers located at the secondary care/district hospital or local private nursing home, if such a facility is available.
- Influenza vaccines can reduce serious illness and death in patients with COPD by about 50% and should be given once (in autumn) or twice (in autumn and winter).^{35,36}
- Other diseases, especially tuberculosis, should be excluded. If the sputum is positive for acid-fast bacilli (AFB), the patient should be referred to the nearest Directly Observed Treatment, Short-course (DOTS) Centre under the Revised National Tuberculosis Control Programme. If a DOTS Centre is not available, anti-tuberculosis treatment should be started as per standard guidelines.
- Through proper registration and follow-up protocols, the auxiliary nurse-midwife (ANM) and medical officer should keep a watch on the progress of the patient, which includes improvement in the symptoms of cough and breathlessness, reduction in sputum production and increased exercise tolerance (e.g. six-minute walking). Periodic visits by the ANM would go a long way in this process. The key role of the family doctor should not be ignored. It is highly recommended to dovetail the efforts of all those concerned with the health of the patient.
- The following patients need to be referred to the secondary/tertiary care level health centre:
 - those with symptoms of cardiac or respiratory failure
 - those not responding to treatment at the primary level
 - those in whom alternate diagnoses are strongly suspected
 - those requiring assistance in tobacco cessation and/or respiratory rehabilitation.

The patient should be referred to a centre where diagnostic and other facilities, including spirometry and inpatient services, are available.

Since the 1960s, beta-2 agonists are the mainstay of therapy for obstructive lung diseases with studies demonstrating sustained improvement in peak flows and respiratory symptoms with their use. However, the literature seems to be accumulating against their regular use as it results in tolerance to their bronchodilator and non-bronchodilator effects, and may lead to exacerbations of asthma and an increase in the number of deaths. A meta-analysis of a number of studies reinforces the accumulating evidence that the use of beta-2 agonists leads to an increased risk for cardiovascular disease. This is of special concern for patients with underlying cardiac conditions. In contrast, cardio-selective beta-blocker therapy is safe in patients with obstructive lung disease and associated with considerable reduction in cardiovascular mortality. As a word of caution, long-term trials need to be undertaken to evaluate the safety and efficacy of beta-2 agonists as against the use of other substances such as ipratropium, corticosteroids or beta-blockers. Until then, a careful, constant watch for any complication in patients with COPD is a must.³⁷

Cochrane's review on COPD

Despite the lack of reversibility, patients often report symptomatic improvement with short-acting beta-2 bronchodilators. These are used for the management of both stable and acute exacerbations of COPD. A meta-analysis of 13 studies showed a slight but significant increase in FEV₁ and FVC when compared to placebo (weighted mean difference [WMD]=0.14 L; 95% CI=0.04, 0.25 and WMD=0.30 L; 95% CI=0.02, 0.58, respectively). In addition, both morning and evening peak expiratory flow rates (PEFR) were significantly better during active treatment than during placebo use (WMD=29.17 L/min; 95% CI=0.25, 58.09 and WMD=36.75 L/min; 95% CI=2.56, 70.94, respectively). A significant improvement in the daily breathlessness score was observed during treatment with beta-2 agonists when compared to placebo (SMD=1.33; 95% CI=1.0, 1.65). The risk of dropping out of the study (treatment failure) was almost double in patients on treatment with placebo as compared to those on treatment with beta-2 agonists (relative risk [RR]=0.49; 95% CI=0.33, 0.73). Patients preferred beta-2 agonists almost 10 times more often than placebo (OR=9.04; 95% CI=4.64, 17.61). One study that used a validated questionnaire for 'quality-of-life' assessment found highly significant improvements in the scores for dyspnoea (p=0.003) and fatigue (p=0.0003) during treatment with salbutamol. No studies have reported serious side-effects during treatment with inhaled beta-agonists. Hence, the use of short-acting beta-2 agonists on a regular basis for at least seven days in stable COPD is associated with improvements in post-bronchodilator lung function and a decrease in breathlessness. This review indicates that treatment with these older, inexpensive drugs is beneficial in patients with COPD. A practical approach at different levels of care has been worked out.³¹

Recommendations

- Organizing mass awareness programmes for the public and health providers to ensure early detection and initiation of treatment with low-cost, effective drugs would go a long way in controlling COPD. As cigarette smoking is the most important risk factor (Table 14), all efforts must be made to reduce and discourage this habit, particularly among the youth and young adults, to achieve overall reduction in the general morbidity, particularly that of COPD.
- The economic burden of COPD on families can be reduced if and only if all health providers strictly adopt the guidelines for early case detection, management and medication with simple and less expensive drugs to start with (Appendix 2).
- The detection of mild cases of COPD and initiation of basic treatment by peripheral health workers/providers with inexpensive drugs would go a long way in early detection and prevent disease progression to moderate

Table 14. Risk factors for COPD³⁸

Factor	Comments
Age	Mainly due to association with cumulative exposure indices
Gender	More common in males, probably due to association with other risk factors
Smoking	Most important factor
Environmental pollution	Specific occupational groups
Economic status	In association with other risk factors

Source: Pande and Khilnani 2001

and/or severe forms. Higher compliance rates for drug use (because the treatment is for a prolonged duration) and referring acute cases to the PHC/local medical doctors would reduce the financial burden of COPD on society. This act in itself would reduce the caseload on the medical doctors at the PHC/subcentre level and enable them to provide better service to other patients. This approach would help to achieve the goal of 'Health for all' in a more effective way.

- Massive training programmes for basic health workers/providers in the periphery to efficiently detect and manage the cases of COPD by adopting the guidelines would ensure success of the programme.
- Efforts should be made to reduce the burden of COPD among patients from rural areas who constitute the bulk of cases and are economically poor. One medical or a trained senior paramedical person should always be available at the PHC to attend to emergencies.
- A public-private stakeholder approach would be the most effective way to combat COPD in India. The involvement of all local medical practitioners/family doctors/pharmacists through trust and ensuring that this approach would not, in any way, affect their practice, would help this approach to succeed.

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Appendix 1

Guidelines for the management of stable COPD²⁷

Diagnosis	Assess lung function (FEV ₁ and vital capacity) using spirometry		Additional supportive measures
Clinical features	Mild	No abnormal signs; smoker's cough; little/no breathlessness	<ul style="list-style-type: none"> • Cessation of smoking is absolutely essential to prevent accelerated decline in the condition. • Encourage exercise to improve performance and reduce breathlessness. • Obesity or poor nutrition should be addressed. • Influenza vaccine is recommended particularly for those with severe COPD. • Depression associated with severe COPD should be identified and treated. <p>Refer a patient with COPD to a specialist in the following situations:</p> <ul style="list-style-type: none"> • Suspected severe COPD • Onset of cor pulmonale • Assessment for oxygen nebulizer or oral corticosteroid therapy • Bullous lung disease • Rapid decline in FEV₁ • Under 40 years of age or having a family history of alpha₁-antitrypsin deficiency • Uncertain diagnosis • Symptoms disproportionate to lung function deficit • Frequent infections
	Moderate	Breathlessness (with/without wheeze) on moderate exertion; cough (with or without sputum); variable abnormal signs—general reduction in breath sounds and presence of wheeze	
	Severe	Breathlessness on minimal exertion or at rest; wheeze and cough often prominent; over-inflation of the lung usual; cyanosis, peripheral oedema and polycythaemia in advanced disease, especially during exacerbation	
Aims	<ul style="list-style-type: none"> • To provide optimal symptom control • To prevent deterioration of condition and complications • To improve the quality of life 		

Table A1.1 Guidelines for the management of COPD

	Mild	Moderate	Severe
Predicted FEV ₁	60%–80%	40%–60%	<40%
Bronchodilator therapy*	Use inhaled short-acting beta-2 agonist or inhaled anticholinergics, as required.	Regular use of inhaled short-acting beta-2 agonist and/or regular inhaled anticholinergics	Regular use of combined inhaled short-acting beta-2 agonist and anticholinergics High doses of bronchodilators (including the use of nebulizer) should only be prescribed after assessment by a specialist. Theophylline should be reserved for those in whom other treatments fail to control symptoms adequately.
Corticosteroid therapy*	Not required	Consider corticosteroid therapy	Perform corticosteroid trial. <i>Corticosteroid trial:</i> 30 mg oral prednisolone for 2 weeks; positive response to reversibility test—give regular inhaled corticosteroids.
Long-term oxygen therapy	Not required	Not required	Assessment of arterial blood gases by a specialist is required. Long-term oxygen therapy is prescribed if PaO ₂ <7.3 kPa and FEV ₁ <1.5 L

*No bronchodilator and/or corticosteroid therapy reversibility tests; a positive response is an increase in FEV₁, i.e. both ≥200 ml and a 15% increase from the baseline.

Note: Positive response to bronchodilator therapy indicates improved likelihood of positive response to corticosteroids. The dose of the bronchodilator and/or corticosteroid may be increased during an acute exacerbation.

Appendix 2

Guidelines for the management of COPD in India: A guide for physicians^{31,34}

Staging the severity of COPD

Table A2.1 Staging of COPD based on symptoms, signs, 6-minute walk test and peak expiratory flow rate (PEFR)

Stage	Symptoms (cough and sputum)	Signs	6-minute walk test	PEFR (optional)
At risk	No dyspnoea, hypersecretion+			
Mild	Dyspnoea on unaccustomed activity or climbing two flights of stairs	Mild hyperinflation	>200 m	50%–70%
Moderate	Dyspnoea on unaccustomed activity	Moderate hyperinflation	100–200 m	30%–50%
Severe	Dyspnoea at rest	Near absence of breath sounds, respiratory failure, polycythaemia and chronic heart failure (CHF)	<100 m	<30%

Table A2.2 Treatment guidelines depending upon the severity of COPD

Mild	Short-acting bronchodilators, when needed
Moderate	Regular treatment with one or more bronchodilators
Severe	As in moderate COPD + inhaled corticosteroids; treatment of complications

COPD should be considered and spirometry performed if any of these indicators are present (Table A2.3). The indicators are not diagnostic by themselves, but the presence of multiple indicators increase the probability of a diagnosis of COPD. Spirometry is needed to establish a diagnosis of COPD.

Table A2.3 Key indicators for considering a diagnosis of COPD

Chronic cough	Present intermittently or every day Often present throughout the day Seldom only nocturnal
Chronic sputum production	Any pattern of chronic sputum production may indicate COPD
Dyspnoea that is	Progressive (worsens over time); Persistent (present every day); Described by the patient as: 'increased effort to breathe', 'heaviness', 'air hunger', or 'gasping'; which is worse on exercise Worse during respiratory infections
History of exposure to risk factors, especially	Tobacco smoke Occupational dusts and chemicals Smoke from home cooking and heating fuels

The use of bronchodilators is the central point in the symptomatic treatment/management of COPD. These are given on an as-needed basis for the relief of persistent or worsening symptoms, or on a regular basis to prevent or reduce symptoms. Long-acting inhaled bronchodilators are more effective and convenient, but also more expensive. Combining various bronchodilators may improve the efficacy and decrease the risk of side-effects compared to increasing the dose of a single bronchodilator.

Guidelines for physicians on tobacco cessation

Follow the 5-A strategy

- Ask (about use)
- Assess (the status and severity of use)
- Advise (to stop)
- Assist (in smoking cessation)
- Arrange (the follow-up programme)

Details of advice to the patient

- Review your tobacco use. Accept that smoking is a problem and harmful for your health.
- Make a decision and be determined to quit. Don't be overconfident that you can quit any time you like.
- Share your decision with family, friends and your doctor. Accept their help.
- Fix a quit date. Don't postpone.
- Remove ashtrays and other objects that are reminders of the habit.
- Keep away from trigger situations.
- Adopt a healthy lifestyle such as relaxation, exercise, good diet with plenty of water, fruits, vegetables and avoid tea/coffee/alcohol.
- Take help from family, friends and your doctor.

First few steps of quitting tobacco smoking

I To reduce quantity

- Change to a non-preferred brand.
- Keep a record of the amount and frequency of tobacco use.
- Decrease the number of puffs when smoking.
- Leave large stubs.
- Don't inhale deeply.

II To deal with triggers when you have an urge to smoke (trigger coping)

- To overcome an extraordinary urge to take tobacco, try alternatives (chewing gum, toffee, peppermint, cardamom).
- Increase your water intake.

- Breathe deeply and quietly.
- Do some other work to engage and keep your mind off tobacco.
- Delay the act of smoking—count till 100 and think of pleasant situations.

Table A2.4 Commonly used bronchodilators in India

Drugs	Metered dose/dry powder inhalers (µg/dose)	Oral
Beta-agonists		
• Salbutamol	100–200	2–4 mg tid/qid
• Terbutaline	250–500	2.5–5 mg tid
• Salmeterol	25–50	
• Formoterol	6–12	
• Bambuterol		10–12 mg/day
Anticholinergics		
• Ipratropium	40–80	
• Tiotropium	18	
Methylxanthines		
• Aminophylline		225–450 mg/day
• Theophylline		200–600 mg/day

Note:

- A combination of a short-acting beta-agonist and the anticholinergic drug ipratropium in stable COPD produces greater and more sustained improvements in FEV₁ than either alone, and does not produce tachyphylaxis.
- The addition of oral theophylline should normally be considered only if inhaled treatments have failed to provide adequate relief.
- Don't use antibiotics except to control bacterial infections and infectious exacerbations.
- Regular use of antitussives should be discouraged in stable COPD.
- Respiratory stimulants, sedatives and narcotics should be avoided because of their respiratory depressant effects.
- Advise proper nutritional intake.
- Initiate rehabilitation programmes particularly for those quitting the tobacco habit.
- The common causes of an exacerbation are infection of the tracheobronchial tree and air pollution. The cause of a third of the exacerbations cannot be identified. Pneumonia, congestive heart failure, pneumothorax, pleural effusion, pulmonary embolism and arrhythmias, which also mimic COPD, need to be excluded. Bronchodilators are the cornerstone of managing exacerbations of COPD. The dose and/or frequency of use of the existing bronchodilator therapy need to be increased. Nebulizers may be used for drug administration. Systemic glucocorticoids should be used in acute exacerbations as they shorten the recovery time and help restore lung function more quickly.

See Appendix 2 in the paper on 'Economic burden of asthma' for the management of COPD. For causal analysis, and medical equipment and drug requirements for COPD, see Appendix 3 of the same paper.

III Once you quit

- Learn to say 'no' to tobacco offers from others. Don't take a single puff.
- Try to remain in smoke-free areas. Avoid the company of smokers and even tobacco-chewers.
- Form a group of people who have quit tobacco and share their experiences.
- Collect the money saved from each pack of cigarettes or *paan masala*. Buy gifts for your loved ones with that money.
- Try alternative ways to deal with mental stress and tension such as relaxation, deep breathing, listening to music.
- Remember that there can be some withdrawal symptoms after quitting, such as headache, irritability, lack of concentration, etc. But bear with them. These are temporary and will disappear in a few days.

Even if you fail to quit smoking

—don't get disheartened, try again.

—seek the help of those who have quit smoking.

—seek professional help and medical advice.

Reduction of other risk factors

- Avoid burning of crop residue.
- Suppress dust by the use of water.
- At the workplace, use a mask in areas of dust generation.
- Use smokeless *chullahs* to reduce the risk associated with solid fuel combustion. Use a thin cloth to cover the nose and mouth near sources of combustion.
- The kitchen should be adequately ventilated.
- Stop/minimize indoor smoking and in front of the children.

Drug treatment

Bronchodilators are central to the symptomatic treatment of COPD. Inhaled drugs are preferred to oral preparations. The availability of the patient and affordability of the drug need to be considered in the choice of drugs. Step-wise treatment is recommended.