

What is the true burden of chronic obstructive pulmonary disease in India and what are its implications at a national level?

According to the global burden of disease (GBD) report, chronic obstructive pulmonary disease (COPD) is the 2nd leading cause of death and disability adjusted life years (DALYs) in India.^[1,2] Based on sophisticated mathematical models developed from only well-designed and executed prevalence studies, mortality data and the burden of risk factors for COPD across India, the 2019 GBD report estimated the COPD prevalence to be 37.8 million. However, at the most, these are only estimates based on the limited amount of existing data. Understanding the true burden of COPD in India is necessary to inform our health-care policy makers and health-care providers to devise COPD-specific preventive, promotive, and therapeutic health-care strategies. However, India is literally a nation within nations with a huge geographic, cultural, and economic diversity. Conducting well-designed and technically sound COPD epidemiological studies across India is a huge challenge.

Earlier epidemiological studies determined the prevalence of COPD using a questionnaire that captured demographic details, symptoms, and exposure to risk factors. However, they lacked adequate sensitivity and specificity to make any reliable estimates. Spirometry was found to have much greater sensitivity and specificity. In fact, the Global Initiative for Chronic Obstructive Lung Disease used spirometry to define COPD, which then became the gold standard.

Spirometry, however, is a difficult test to perform not only because it is an effort-dependent test and requires patient cooperation but also because it needs a well-trained and patient technician who performs good quality spirometry.^[3] To confirm the diagnosis of COPD, it is necessary to perform two spirometry tests, a prebronchodilator and a postbronchodilator test after giving an inhaled short-acting bronchodilator through a pressurized metered dose inhaler and spacer or a dry powder inhaler and waiting for at least 20 min between the two tests. Prebronchodilator forced expiratory volume in 1 s/forced vital capacity (FEV₁/FVC) only suggests the presence of obstructive airways diseases and cannot be used to define COPD. Furthermore, the correct way of interpreting spirometry to define COPD is still debated. Should a fixed value of <0.7 be used for the FEV₁/FVC ratio, or should the lower limit of normal (LLN) be used?^[4] Should COPD be defined based only on the spirometry report or should the symptoms be also taken into account?

This lack of clarity for defining COPD and the challenges encountered in performing spirometry have demotivated epidemiologists to conduct COPD prevalence studies. An earlier systematic review of previously published studies from India in 2012 revealed not a single study that met the quality standards.^[5] The authors, however, estimated a crude prevalence rate of chronic bronchitis based on the questionnaire only to be roughly between 6.5% and 7.7% in the rural areas only.

Since 2012, there have been several attempts to conduct good quality COPD prevalence studies in India. At least four sites across India took part in the burden of obstructive lung disease study, an international study using a robust design and standardized and validated questionnaires along with a postbronchodilator spirometry test. Over the last decade, several others have also used this methodology to study the burden and risk factors for COPD in India. In this issue of the journal, Daniel *et al.*^[6] report a systematic review and meta-analysis of eight such studies conducted in different parts of India (total sample size of 8659, 49.2% males). Among the eight studies, 4 were from northern India, 3 from southern India, and 1 from the eastern region. Five of the eight studies were conducted in rural areas, whereas three studies were conducted in urban cities. Using random effects pooled estimates, they reported the prevalence of COPD in India to be 7.4% (95% confidence intervals: 5%–9.8%). The COPD prevalence was 11% in urban areas, whereas in rural areas, it was 5.6%. Using these prevalence rates, and the fact that 34.9% of the India's population (1.39 billion according to the 2021 United Nations data) live in the urban areas and 65.1% live in the rural areas, and that COPD occurs at a younger age in India (>35 years) like in other low- and middle-income countries,^[7] the estimated burden of spirometry-defined COPD in India is 37.6 million. This is surprisingly similar to the GBD 2019 estimates for COPD prevalence in India (37.8 million). Using the reported 95% confidence intervals by Daniel *et al.*, the COPD burden in India will likely range from 25.1 million to 49.2 million.

It has been generally agreed upon that the postbronchodilator FEV₁/FVC ratio <0.7 or the LLN identifies all patients of COPD characterized by the two distinct structural processes, namely (a) emphysema due to alveolar wall destruction and poor elastic recoil of lungs and (b) small airways narrowing and remodelling. However, concerns have been raised about the sensitivity of spirometry to detect

all cases of COPD. In 1986, Bergin *et al.*^[8] reported that spirometry can be normal even when 20%–25% of the lung showed emphysema on computed tomography (CT) scan. In 2016, Woodruff *et al.*^[9] reported that respiratory symptoms were common in current or former smokers despite normal FEV₁/FVC and FVC values. These subjects reported significant respiratory exacerbations, a shorter 6-min walk distance and needed regular medications. In 2019, Regan *et al.*^[10] reported that in the COPD gene study involving 10,192 smokers, spirometry missed 42.3% of patients having emphysema (reported in 24% patients) or airway disease (reported in 31% of the patients). When compared with high-resolution CT (HRCT) scan, these subjects with normal spirometry but HRCT evidence of emphysema or small airways obstruction, had poor quality of life, recurrent exacerbations, increased hospitalizations and deaths, similar to patients with spirometry-defined COPD.^[11] Similar observations have been reported from the other parts of the world,^[12] highlighting the fact that spirometry-defined COPD under-diagnosis a significant proportion of clinically relevant COPD. The true burden of COPD in India is therefore likely to be much higher than the estimated 37 million and likely to be close to around 50 million.

Should we be worried about COPD in India? COPD alone accounts for over 9.5% of the total deaths in India (GBD 2019 Report). Out of the chronic respiratory disease burden in India, COPD accounts for over 50% of the disease burden and 70% of the years of life lived with disability. COPD is caused not only by tobacco smoking but also by a wide variety of different nonsmoking causes,^[13] which account for 48% of COPD deaths and 51% of COPD DALYs in India (GBD 2019 report). There are 120 million tobacco smokers in India, over 60% of Indian population lives in homes where biomass fuel still continues to be used for cooking or heating purposes, between 56% and 76% of households in India use various types of mosquito repellents,^[14] over 35 million people are engaged in the dusty building and construction industry, road sweepers, hawkers, rickshaw/taxi/bus drivers, traffic policemen, are all chronically exposed to high levels of ambient air pollution. Pulmonary tuberculosis and poorly treated asthma, which are important risk factors associated with COPD, are highly prevalent in India. Early life represents a critical period for the development and growth of the lungs. A recent systematic review and meta-analysis of 30 studies reported that childhood serious respiratory infections/pneumonia/bronchitis (Pooled odds ratio [OR]: 2.23; [1.6–3.0]), childhood asthma (OR: 3.45; [2.3–5.0]), childhood abuse (OR: 1.3; [1.2–1.4]), maternal smoking (OR: 1.42; [1.1–1.7]) and low birth weight (OR: 1.58; [1.1–2.3]) were all associated with a significantly increased risk of adult COPD.^[15] India is a fertile country for COPD, with a huge burden of risk factors associated with COPD that are widely prevalent across the country.

Despite the huge and growing burden of COPD in India, over 98% of people living in urban slums of Pune city

and its surrounding rural villages have never heard the word COPD.^[16] A call for a National COPD Prevention and Control Program was made in the past,^[17] yet very little has changed at the health-care policy level.

India now needs to start taking COPD very seriously. A recent American Thoracic Society workshop made ten specific recommendations for a country like India to tackle COPD effectively,^[18] namely (1) national respiratory societies should provide country-specific COPD management guidelines; (2) patient and professional organizations must persuade policy-makers of the importance of lung function testing programs; (3) health-care education and training should emphasize the early-life origins of COPD; (4) urgent action is required by governments to reduce airborne exposures, including exposures to tobacco smoke and indoor and outdoor air pollution; (5) guidance for COPD should explicitly link across Essential Medicine Lists and the World Health Organization package of essential noncommunicable disease interventions for primary health care in low-resource settings and should consider availability, affordability, sustainability, and cost-effective use of medicines; (6) the pharmaceutical industry should work to make effective COPD and tobacco-dependence medicines globally accessible and affordable; (7) implementation of locally adapted, cost-effective pulmonary rehabilitation programs should be an international priority; (8) the World Health Organization Global Action Plan for the Prevention and Control of Noncommunicable Diseases should specify how improvements in respiratory health will be achieved; (9) research funders should increase the proportion of funding allocated to COPD; and (10) the respiratory community should leverage the skills and enthusiasm of earlier-career clinicians and researchers to improve global respiratory health. This blueprint suggested by the American Thoracic Society, if implemented, will contribute significantly to reducing the burden of COPD in India. It is now time to start taking COPD seriously before the burden of COPD overwhelms our health-care system and economy.

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