COPD in India: Iceberg or volcano?

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ABSTRACT

The purpose of this article is to provide an overview of the epidemiology of COPD in India which is one of the most affected countries in the world and contributes significantly to the mortality and morbidity of this disease; to provide insights into the etiological determinants of COPD in India; comment on treatment aspects including drug treatment, adherence to guidelines, treatment of exacerbations and to try to comment on whether it differs significantly from rest of the world. The article reviews published literature on COPD in India; provides insight into comparative methodologies involved; comments on gaps in knowledge and suggests areas of further research such as Prescription Audit. India contributes very significantly to mortality from COPD 102.3/100,000 and 6,740,000 DALYs out of world total of 27,756,000 DALYs; thus significantly affecting health related Quality of Life in the country. COPD is surpassing Malaria, TB even today and the gap would get wider with time in near future. The lack of robust real time nation-wide data does plague India as well, however multiple studies from 1994 to 2010 show increasing trends of COPD morbidity and mortality. Since most inhalational drugs are available in the country there is no reason why mortality should not be comparable to rest of the world but there is poor adherence to treatment guidelines, both national and international. Urban centers in India are comparable to their global counterparts in terms of service quality and facilities and this is also work in progress. However, the rural hinterland is poorly serviced; national GDP spending on health is remarkably low. Some innovation is emerging and that could be the harbinger of a new future if properly nurtured. The article is an overview of COPD in India with emphasis on understanding the multi-dimensional nature of the problem and an attempt of providing insight into possible de-bottlenecking to reduce the pain and suffering of millions of COPD patients in India in future.

KEY WORDS

COPD; chronic bronchitis; emphysema; India; epidemiology

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Introduction

Like everywhere else in the world and especially in the developing world; India is changing - not only in terms of its demographics, urbanization, economic profile, pollution but also in terms of its health burden, disease pattern, dominant-diseasecomposition, morbidity and mortality determinants.

Like China, India also contributes a significant and growing percentage of COPD mortality estimated to be amongst

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However, what needs to be remembered in analyzing any such or similar data is that the devil often lies in the details and methodological considerations often add a different dimension to such data figures. Common sense and wisdom dictates that the morbidity and mortality for individual diseases - if reduced; can help decrease the overall mortality. For example, reducing annual chronic disease death rates by every 2% can easily avoid 36 million deaths cumulatively by year 2015 (3).

COPD is a gradually progressive disease which manifests late and as such most methodologies are likely to under estimate the morbidity and mortality rates of this disease, worldwide. In developing countries resource constraints often dictate the methodology of gathering data and inability to conduct large

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Figure 1. COPD Mortality Projections: Global Burden of Disease Data. Updated 20th January 2011.

Table 1. Prevalence of COPD and its association with smoking in various population studies from India: Early studies 1964 to 1995.							
	Decidetien	COPD prevalence (%)					
	Population -	Men	Women	M:F Ratio			
Wig [1964]	Rural Delhi	3.36	2.54	1.3			
Sikand [1966]	Delhi	7.0	4.3	1.6			
Viswanathan [1966]	Patna	2.12	1.33	1.6			
Bhattacharya [1975]	Rural U.P	6.67	4.48	1.6			
Radha [1977]	New Delhi	8.1	4.6	1.8			
Thiruvengadam [1977]	Madras	1.9	1.2	1.6			
Viswanathan [1977]	Delhi Rural	4.7	3.5	1.3			
	Urban	8.0	4.3	1.9			
Charan [1977]	Rural Punjab	2.28	1.63	1.4			
Malik [1986]	N.India Rural	9.4	4.9	1.9			
	Urban	3.7	1.6	2.3			
Jindal [1993]	N.India Rural	6.2	3.9	1.6			
	Urban	4.2	1.6	2.6			
Ray [1995]	South India	4.08	2.55	1.6			

scale Spirometry Based surveys often compromise quality of data gathered and estimated from questionnaire based methodologies. However consistent patterns of trends emerging over long periods despite different investigators addressing the same disease; does help generalize the epidemiological significance of the disease. COPD prevalence, morbidity and mortality data from India perhaps falls into this category.

The prevalence of COPD has been studied extensively by

Indian investigators over the last 5 decades. These studies were characterized by local initiatives and could not be generalized on a national level. However, in spite of the localized nature of these studies they did provide a trending data at major urban centers in the country. These studies were comprehensively reviewed by Jindal S. K. *et al.* subsequently (4) (Table 1). The COPD prevalence varied from 3% to 8% amongst Indian males and approximately 2.5% to 4.5 % among Indian females.

	1	Vales	Fen	nales		Total	
Year	Urban	Rural	Urban	Rural	Urban	Rural	
1996	2.34	6.38	1.12	3.16	3.46	9.54	
2001	2.66	7.26	1.32	3.70	3.98	10.96	
2006	3.02	8.23	1.51	4.26	4.53	12.49	
2011	3.43	9.35	1.72	4.83	5.15	14.19	
2016	3.94	10.76	1.97	5.54	5.91	16.30	

Between 2002 and 2005, a landmark and very detailed study was undertaken in Delhi-the national capital by the Central Pollution Control Board of India and it included all possible components of investigation including ambient air quality, Respiratory Health Questionnaire Survey, Spirometry of randomized sections of Delhi population with control population from West Bengal rural areas. It had very robust methodology studying Sox, NOx, VOCs, RSPM, PM10, and Hydrocarbons amongst the air pollutants and hematology, cell cytology, molecular biology of blood cells, airway epithelial cells, mediators of injury in sputum and buccal and airway epithelium studied over a long period and documented extensively (5).

Space restraints won't permit me to mention its detailed findings here but suffice it to say that the study established the multi-factorial links between air pollutants, smoking behavior and respiratory and cardiovascular morbidity unequivocally and helped pave the way for citizen activism and environmental intervention in a unique way. The COPD prevalence in Delhi residents was close to 4% in this study. Indoor pollution determinants and ambient air quality parameters were also significantly high and contributed significantly to respiratory symptom burden in this study though a clear correlation with Spirometry-defined-COPD was not established (5).

Around 2004-2006 Indian Council of Medical Research commissioned a four city multi-center survey based on validated symptom questionnaire methodology targeting 35,000 urban and rural residents; the INSEARCH-I study. Prevalence of COPD was documented to be around 4.1% (5% males to 3.2% females). Smokers had 3 times more risk to develop COPD as compared to non-smokers and Bidi smokers were at higher risk of developing COPD (8.2%) than their Cigarette smoking counterparts (5.9%). Cooking fuel exposure was documented from 2% using LPG to around 5% using Kerosene and/or biomass fuels or firewood. No statistically significant differences could be established between different fuel types among the non smoker populations (6). Odds of developing COPD amongst non-smokers exposed to ETS and Fuel smoke both were higher than for ETS exposure alone (OR 1.576). The Global Burden of Disease study by Murray & Lopez in 1996 predicted global prevalence of COPD to be 9.34 per 1,000 for males and 7.33 per 1,000 for females of all ages (7).

The National Family Health Survey conducted nationwide in 1998-1999 by Indian Institute for Population Sciences, Mumbai was also published in 2000. It covered almost the entire nation including the sub-Himalayan states with comprehensive coverage. The prevalence of smoking in above-30-year age group was 40.9% among males and 3.9% amongst females. For the under 20 age group this prevalence was 4.5% and between 20 and 29 it was around 14% among males. Tobacco and Pan Masala chewing was very widely spread among both sexes especially in the hilly states and so was alcohol consumption in tribal populations (8).

The National Commission on Macroeconomics and Health was set up to study various diseases and their burden on the health care system of the country in 2001 and the COPD burden estimated and projected by them was an eye opener for clinicians and policy makers alike. The commission used population estimates starting 1996 and projected population growth till 2016 as per census of India statistics. Expected changes in mortality figures were applied as required (Table 2). Cost of treatment estimates were based on review of older published studies from 1992 to 1999 and incremental cost estimates were applied dependent on projected inflation rates. According to the NCMH estimates; in 2006 there were around 17 million COPD patients in India and in the next 10 years this figure is likely to reach around 22 million (9) (Figure 2).

The NCMH estimates of prevalence of COPD showed that the burden of COPD is more in rural India and is increasing all the time. A pilot study conducted in Hyderabad was assumed to indicate acute exacerbation rates amongst Indian COPD patients and a rough estimate of acute cases for the same period was done which also showed increasing trend and additional economic burden (Table 3) The economic burden of COPD was estimated in Crores of Rupees (1 Crore =10 Million). As per these estimates the current estimated burden of COPD for India is 35,000 Crore Rs. or 350,000 Million Rs. (Rs. 350 Billion). This is likely to reach a staggering 48,000 Crore Rs. (Rs. 480 Billion) in next five years. This current cost, however, assumes that the practice of treating COPD remains what it was when these estimates were made, 2001-2005. If, however the medical community were to adhere to standardized national and international treatment guidelines this cost could drastically come down to Rs. 41 Billion today 2011-2012 and up-to Rs. 56 Billion in 2016 (9) (Figure 3).

Whereas the NCMH data can be analyzed and criticized for its approximations of cost of treatment; other studies published around the same period corroborate the prevalence estimates.

The WHO country unit for India compiled the Morbidity and mortality data from Non-Communicable diseases for the



Figure 2. Estimated number of cases of COPD in India in the current decade.

Year	Males		Females		Total no. of acute cases		
	Urban	Rural	Urban	Rural	Urban	Rural	Total
1996	.069	.189	.062	.175	.131	.364	.495
2001	.078	.213	.072	.202	.150	.415	.565
2006	.089	.244	.083	.235	.173	.478	.651
2011	.103	.282	.097	.272	.200	.554	.754
2016	.120	.328	.113	.318	.234	.647	.881

country from 1998 to 2002. Nongkinryh *et al.* published this in Journal of Association of Physicians of India in 2004. COPD and Asthma were second leading cause of death after Road Traffic Accidents (Figure 4). The morbidity figures showed them to contribute to around 55 million cases for both Asthma and COPD combined (10) (Figure 5).

A retrospective analysis of the Registrar General of India data based on 5 years moving averages between 1966 to 1994 and further corroborated with the census data of 2001 (excluding the hilly regions of the country); where NFHS I & II were also available published in the Internet Journal of Epidemiology in 2005 showed a distinct trend of COPD overtaking Tuberculosis and Pneumonia as leading cause of death for this period (11) (Figure 6).

That Tuberculosis and Malaria mortality has been falling

and shall continue to fall has been corroborated by another Policy paper from WHO published in 2005 (12). Tuberculosis mortality is expected to fall from 0.4 million currently to 0.2 million by 2030. Whereas COPD mortality is expected to increase from 0.9 million as of now to about 1.6 million in parallel with the worldwide trends (12) (Figure 7).

Any future projections can be viewed with skepticism and hence more important than these estimates - a better documented data available from the state of Maharashtra is more relevant. COPD was found to be the leading cause of death ahead of Cardiac Arrest, Stroke and Ischemic Heart Disease combined together. The data has been compiled by the Health Management Information System (HMIS), the Sample Registration System (SRS), the Survey of Cause of Death (SCD), etc. Though this is data from only one major state, it is very much possible that other states in peninsular India are no different (13) (Figure 8).

Mortality is just one aspect of a debilitating disease like COPD. The Health Related Quality of Life is severely affected by the disease as well. The sub-optimal living along with premature mortality is expressed as Disability Adjusted Life Years or DALYs. World wide it is estimated that nearly 28,000 (Thousands) DALYs were lost due to COPD in 2002. A large chunk of this loss came from Western Pacific Region of WHO dominated by China (9,500,000 DALYs) and from South Asia region of WHO dominated by India (6,740,000 DALYs). These two nations are harboring 33% humanity; and contribute to a 50% colossal loss of life years. The disease which was ranked 12th in 1990 in terms of DALYs lost is going to rank 5th in 2020 in the



Figure 3. Estimated economic burden of COPD in India as per current practice and savings achievable if guidelines were implemented.



Figure 4. Estimated mortality due to non-communicable diseases in India.



Figure 5. Estimated morbidity due to non-communicable diseases in India.



Figure 6. Leading causes of mortality in rural India from 1966-1994.



Figure 7. Mortality trends of communicable diseases & COPD in SEARO region.



Figure 8. Major mortality determinants in Maharashtra State 2008.



Figure 9. Estimated DALYs lost to COPD by various regions of WHO.

hierarchy of all diseases (14) (Figure 9).

A recently concluded Respiratory Questionnaire based survey of 12 cities labeled Indian Study of Asthma, Respiratory Symptoms and Chronic Bronchitis (INSEARCH-II) is yet to publish its results. Some data on file has kindly been made available to me by one of the investigating team members and further statistical analysis is pending. Considering district as a unit, urban and rural populations have been studied extensively with a previously validated questionnaire survey instrument and a fairly robust data set is likely to emerge which is likely to substantiate the fact that close to 20% of urban Indian males continue to smoke and less than 1% females smoke. It is also likely to shed more light on indoor pollution and its role in COPD prevalence. Rural residence, lower socio-economic strata, advancing age and smoking habit are likely to be major factors favoring COPD development if preliminary analysis is substantiated by further analysis.

Since rural poor staying in ill ventilated houses using dry wood as fuel are likely victims of indoor air pollution; the prevalence among non-smoking females from this subset may throw significant light on the non-smokers' COPD prevalent in India (15) (Figure 10).

The non-smoker's COPD is an entity which needs to be documented in greater detail and this task has to be done by researchers in Asia, Africa, Latin America and other developing regions of the world. COPD among non-smokers may turn out to be a misery seeking missile. A study of 12,000 slum dwellers from Pune in Maharashtra revealed a questionnaire based COPD prevalence rate of 6.5% (8.5% in males and 4.5% in females). Of those diagnosed with COPD, 69% were never smokers. Absence of a separate kitchen for cooking was an independent risk factor associated with COPD prevalence in males (OR=1.95, P=0.02) while use of kerosene fuel for cooking increased the odds of COPD in females by around 2.5 times (OR=2.48, P=0.01) (16) (Figure 11).

Tuberculosis sequelae and COPD

India has remained the Tuberculosis capital of the world for far too long. MDR Tuberculosis continues to be on the rise. However healed tuberculosis with structural sequelae continues to contribute to significant respiratory morbidity in India and other developing countries of the world. COPD as defined by post bronchodilator FEV1/FVC ratio of less than 0.7 has been defined as Post TB COPD for many years (17). Studies from India indicate that healed Tuberculosis with or without significant X-ray abnormality (Up-to 48% of healed Tuberculosis) have COPD based on the spirometry criteria. The longer the duration post completion of anti-tuberculosis treatment, the longer is the chance of developing spirometry



Figure 10. Non-smoker's COPD - misery seeking missile?



Figure 11. COPD amongst non- smokers Is indoor pollution the culprit?

positive COPD. Relative risk of 26% at 5 years post Anti-TB-Treatment (ATT) increases to 41% at 10 years post ATT (18). One could perhaps argue whether this is indeed COPD or not especially if there is no history of smoking or exposure to noxious gases or particulates in home or work environment. However, with increasing awareness of non-smoker's COPD, the role of other aerosols becomes equally important and even in absence of this history, post TB COPD may increasingly be accepted as a separate phenotype. There is an urgent need for further research in this area.

Therapeutic aspects of COPD in India

For historical reasons, to make medicines available to its billion plus poor population; India made certain changes in its patent laws whereby Indian Pharmaceuticals can manufacture many drugs by the "process patent" route rather than the "product patent" route. This has kept the prices of drugs at affordable levels to a large extent and also increased availability of multiplicity of brands in the Indian market. As such there are close to a dozen Indian pharmaceutical companies manufacturing inhaler formulations or DPI formulations for Asthma and COPD. Triple drug combinations - containing inhaled corticosteroids, bronchodilators (LABA), plus anti muscarinic drugs like Tiotropium (LAMA) - have been cleared by Indian FDA nearly five years ago. Unique combinations such as LABA plus LAMA or LABA + ICS combinations such as Formoterol plus Fluticasone have also been available for a fairly long duration. There is an urgent need to do research in therapeutic audits in both Asthma and COPD about the various combination therapies by inhalational route. This will not only help Indian patients but also benefit other emerging medical markets & economies. As of now, there seems to be a paucity of data about these formulations, not going beyond clinical trial data submitted to Indian FDA (19).

Pulmonary rehabilitation aspects

Considering the fragmented nature of the healthcare delivery industry in India, there are no big centers of excellence in India providing protocolized rehabilitation services as in the western world. Mostly individual physician initiatives lead to rehabilitation in informal un-structured manner. A recent study from Manipal demonstrated the utility of improvised unsupported upper limb exercise (UULE) and lower limb exercise (LLE) in COPD rehabilitation with improvement in health related QOL parameters, 6MWD, and chronic respiratory questionnaire for fatigue, emotion, and mastery (20) (Figure 12).

In the rapidly evolving corporate hospitals in major urban centers of India, the physiotherapy, respiratory therapy, occupational therapy departments are helping clinicians shoulder the burden of COPD rehabilitation programs. Traditional medicine practitioners and Yoga and physical medicine practitioners are other important contributors to the rehabilitation effort at some centers. Data about efficacy of some of these techniques is however rather sketchy and not well publicized and peer reviewed.

Treatment of exacerbations of COPD

Acute exacerbations of COPD are more or less treated as per standard international norms. Non invasive positive pressure Ventilation (NIPPV) has become common place in most secondary and tertiary hospitals in India and the ever growing numbers of Intensive Care Units are making ventilatory care available to more and more patients with every passing day (21).

Long term oxygen treatment and home ventilation

Last two decades have seen opening of the Indian economy with removal of restrictions on imports of life saving equipments and as such home oxygen therapy and home ventilation in selected patients of Severe and Very Severe COPD is no longer a novelty in most urban centers in India. However the country is very diverse and generally speaking, rural areas are not adequately serviced. Western and Southern parts of the country - along with urban centers of northern & eastern India - usually have easy accessibility to these facilities whereas the eastern parts of the country including the Hilly States of Sub - Himalayan ranges and the North Eastern States are somewhat lagging behind.

Surgical and non surgical lung volume reduction treatment modalities

This is an area of COPD treatment that has not yet developed in India to its full potential. Lung Volume Reduction Surgery is an important modality in severe COPD patients and the requisite surgical team work is often not available even in many urban centers in the country. Neither Spiration nor Zephyr Endo-Bronchial Valve is as yet approved by Indian FDA and as such not available to physicians or patients yet.

Smoking cessation, primary prevention

Legal ban on smoking in public places is in place but often not adequately implemented. Bidi industry which is as much a problem as the cigarette industry in furthering the COPD epidemic is not necessarily targeted by social and political activists on health promotion grounds as it employs a huge mass of marginalized vote bank sections of the society. Smoking cessation initiatives as CSR activities (Corporate Social Responsibility) are however taking good routes in urban



Figure 12. Unsupported Upper Limb Exercise (UULE).

industrialized centers in the country. This area of primary prevention; though the most cost effective is very poorly documented.

National Urban Health Mission and National Rural Health Mission

Healthcare is on the concurrent list as per the Indian constitution which means both Central and State Governments have a joint responsibility of providing healthcare to the people. The multi party system of democracy with a politically alert opposition and civil society and more demanding middle class has made the Central Government launch the National Urban and Rural Health Mission program in the last 6 years. India has a lack luster record of Government Spending on health as percentage of per capita income or national GDP. The government is trying to correct this anomaly through these programs. However over-politicization, corruption, federal structure and lack of political consensus are some of the bottlenecks in its orderly implementation. As always it is the marginalized and the poor who suffer the most. COPD has been included in the Non Communicable Diseases list of priority health problems in both the Urban and Rural health missions. Effective implementation of the stated program objectives will decide whether India wins this battle against COPD or not.

China and India are bearing a disproportionate burden of COPD morbidity and mortality. Since both countries together constitute one third of humanity, there is potential for cooperation between academia and researchers from the two countries for evolving unique Asian strategies which will not only benefit their citizens but also other neighboring nations as well.

Whether the current epidemic of COPD in India is just a tip of an iceberg or a volcano waiting to erupt will largely depend on these societal responses.

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