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ORIGINAL ARTICLE

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Respiratory questionnaire-based analysis of awareness of COPD in a large multicenter rural population-based study in India

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a more prevalent chronic lung disease with a significant health burden, and the majority of these cases receive inadequate treatment.

Methods: Prospective, observational, interview (questionnaire) based complete workup COPD study, screened 12,000 cases with chronic respiratory symptoms with cough, sputum production, and shortness of breath. A total of 6000 COPD cases were enrolled after the spirometry test. COPD cases were assessed as disease knowledge and methods of treatment offered by applying questionnaires to patients and treating physicians.

Results: In the present study, 3% of study cases were aware of their COPD illness, 54% were not having knowledge about the disease, and 43% cases were not accepting the COPD diagnosis ($p < 0.0001$). A total of 58% of cases received inhalation treatment as levosalbutamol monotherapy in 31% cases, levosalbutamol plus beclometasone in 18% cases, and formoterol plus budesonide or salmeterol plus fluticasone only in 9% of COPD cases ($p < 0.0001$). Total 42% cases received oral treatment as theophylline in 16% cases, salbutamol in 7% cases, oral steroids in 19% cases ($p < 0.0001$).

Conclusion: "Doctor–patient–drug trio" discordance clubbed as "difficult doctor, difficult patient, and difficult treatment" is a very crucial issue observed during diagnosis and management of COPD in peripheral settings in India.

KEYWORDS

chronic obstructive pulmonary disease, difficult doctor, inhalation treatment, salmeterol fluticasone, spirometry

Research Highlights

COPD is an underestimated chronic lung disease and is halfheartedly treated in rural settings in India. In the present study, we observed that 43% of cases were difficult to accept COPD diagnosis, 91% of cases did not receive rational inhalation treatment, and 42% of cases were treated with oral medicines over rational inhalation treatment.

1 | INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is the second leading cause of death in India, affecting almost 53 million people respectively.[1] Various Chronic respiratory diseases are common in India including COPD, asthma, bronchiectasis, interstitial lung diseases, and post-tuberculosis obstructive airway diseases. According to the global initiative for obstructive lung disease (GOLD) 2021 guidelines, COPD is defined as a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases.[2] COPD includes chronic bronchitis, emphysema, and small airway disease. chronic bronchitis is the clinical definition, emphysema is the radiological definition, and small airway disease is the spirometry definition. Chronic bronchitis is defined clinically as the presence of chronic productive cough for 3 months on most days for 2 consecutive years and other causes of cough are excluded. Emphysema is an abnormal, permanent enlargement of the air spaces distal to the terminal bronchioles, accompanied by destruction of their walls and without obvious fibrosis.

Although exact data on COPD disease prevalence, and its impact is not available due to diverse population and cultural trends here in India with a 1.35 billion-plus population, few published studies have documented the prevalence of asthma and COPD, in particular, geographical settings in India.[3–6] The National Health Policy of India 2017 recommends that premature mortality from noncommunicable diseases, including chronic respiratory diseases, should be reduced by 25% by 2025.[7] COPD awareness has a positive impact on disease diagnosis and rational treatment due to heterogeneous trends of practices in the country as varieties of therapies (Allopathy, Homeopathy, Ayurveda, Unani and others) are involved in the treatment of these conditions and nearly two-third cases are still undiagnosed, only one- fifth are getting rational inhalation treatment. Spirometry has a vital role in the diagnosis of COPD including other obstructive airway diseases, including asthma, helps in assessing the severity of illness, predicts prognosis, helps in guiding rational inhalation treatment, and is recommended by GOLD. Spirometry facility is not available in the majority of centers in the country with its limited use due to lack of awareness, although it is the most cost-effective test to diagnose COPD.[8–10] GOLD guidelines recommend Inhalation treatment with combinations of long-acting beta-2 agonists (LABA), long-acting antimuscarinic agents (LAMA), and inhaled corticosteroids (ICS) as frontline therapy for COPD. Various inhalers are available in India ranging from short-acting drugs salbutamol to long-acting salmeterol/formoterol with inhaled corticosteroids and tiotropium; the former being cheaper and available in the majority of government hospitals, also while later being the costlier and not available in government hospitals.[11] In this study, we have studied awareness of COPD as disease knowledge, diagnosis trends, spirometry use, and rational inhalation treatment in rural zones of India.

2 | METHODS

2.1 | Data source

Prospective, observational, interview (questionnaire) based complete workup COPD study conducted from January 2016 to December 2019 in chest diseases department in Venkatesh Chest Hospital & MIMSR Medical College Latur after institutional review board and ethical committee approval. A total of 12,000 cases with chronic respiratory symptoms with cough, sputum production, and shortness of breath that lasted for more than 3 months were screened for a spirometry test. Finally, we enrolled 6000 COPD cases diagnosed by spirometry and written-informed consent-taken format in all cases as a study protocol.

2.1.1 | Inclusion criteria

All cases above 35 years of age with respiratory symptoms such as cough, with or without sputum production, and shortness of breath lasted for more than 3 months, and other causes of the same in tropical settings were ruled out.

2.1.2 | Exclusion criteria

Cases with chronic respiratory symptoms and having an alternative etiological diagnosis as past history of tuberculosis, bronchiectasis, interstitial lung diseases, and lung abnormality on chest radiograph documenting alternative diagnosis.

2.2 | Study design

The respiratory questionnaire (RQCOPD) is developed by an expert group of teaching faculties of two institutes and used during interview and assessment before spirometry: response to each of the following questions noted as *yes*, *no*, and *don't know* (Supporting Information: Annexure I). The RQCOPD is validated by an expert group of pulmonologists after analysis of sensitivity, specificity, positive and negative predictive values, and κ coefficient of agreement is obtained.

2.3 | Methodology (Figure 1)

Case definitions considered in this study formulated by an expert group of teaching faculties in two tertiary care institutes were:

1. "Difficult patient": considered as when patients were not convinced or not ready to accept COPD disease and rational inhalation treatment in spite of spirometry abnormalities suggestive of disease with symptoms and knowing benefits of inhalation treatment over other options.
2. "Difficult doctor": considered as when primary treatment providers were not convinced or not ready to start inhalation treatment in COPD disease in spite of knowing the benefits over other treatment options.
3. "Difficult treatment": considered as when the patient economic status is unable to take rational inhalation treatment in COPD in spite of prescription from a health care expert and patient himself knowing advantages or make aware of it over other treatment options.

All cases were subjected to sputum examination and chest radiograph to rule out infective etiology in view of chronic respiratory symptoms and then spirometry analysis for confirmation of COPD diagnosis. Spirometry tests showing postbronchodilator FEV1 (forced expiratory volume in the first second)/FVC (forced vital capacity) <0.7 were considered as the cut-off for obstructive airway disease and positive bronchodilator reversibility as improvement in FEV1 by at least 12% and 200 ml over prebronchodilator value after fulfilling acceptability and reproducibility criteria as per GOLD guidelines and ATS/ERS task force recommendations.[12] Cases meeting the criteria for obstructive airway disease and having negative bronchodilator reversibly were enrolled as confirmed COPD study cases of COPD.

2.4 | Statistical analysis

The statistical analysis was done using a single proportion test (Chi test) in R-3.4 software. Significant values of χ^2 were seen from the probability table for different degrees of freedom required. A value of p was considered significant if it was below 0.05 and highly significant in case it was less than 0.001.

3 | RESULTS

3.1 | Covariates

In the study of 6000 COPD, 68.33% of cases were males and 31.66% of cases were females, with ages between 35 and 91 years (54.5 ± 17.5 years). The main symptoms in the study group were shortness of breath, cough especially dry, sputum production, fatigability, and chest discomfort. Risk factors were smoking, smoking plus biomass fuel, biomass fuel exposure, and agricultural dust or working in a dusty environment (Table 1). The staging of COPD as per GOLD guidelines, spirometry test (FEV1/FVC < 0.7) results and exacerbations history are presented in Table 1.

TABLE 1 Characteristics of enrolled patients ($n = 6000$)

Characteristics	*n* (%)
Age group	
≥55 years	3602 (60.03)
<55 years	2398 (39.96)
Gender	
Male	4100 (68.33)
Female	1900 (31.66)
Risk factors	
Smoking	804 (13.40)
Smoking plus biomass fuel	408 (6.80)
Biomass fuel exposure	2868 (47.80)
Agricultural dust or work in dusty environment	1920 (32.00)
Symptomatology	
Shortness of breath	5096 (84.93)
Cough especially dry	4149 (69.15)
Sputum production	3669 (61.15)
Fatigability	1869 (31.15)
Chest discomfort	770 (12.83)
Exacerbations history	
0 to 1 not requiring hospitalization	2469 (41.15)
>2 or >1 requiring hospitalization	3531 (58.85)
GOLD staging	
1	609 (10.15)
2	2091 (34.85)
3	1760 (29.33)
4	1540 (25.66)
Spirometry test (FEV1/FVC < 0.7 in all cases) with	
FEV1 ≥ 80%	891 (14.85)
FEV1 50% to <80%	1809 (30.15)
FEV1 30% to <50%	2109 (35.15)
FEV1 < 30%	1191 (19.85)

Abbreviations: FEV1, forced expiratory volume at one second, FVC: forced vital capacity; GOLD, Global initiative for obstructive lung disease.

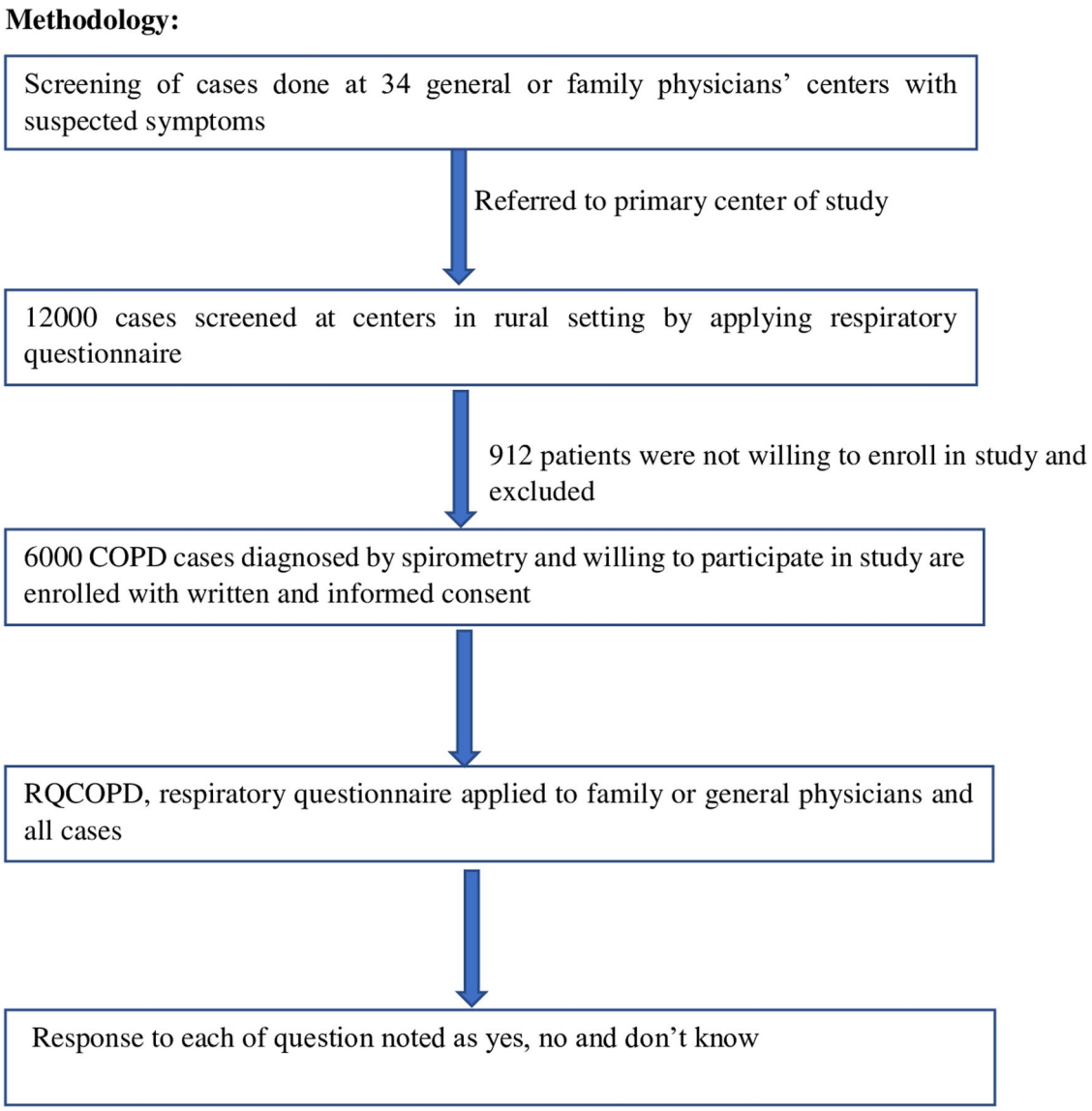

FIGURE 1 Flow of the study

TABLE 2 Treatment methods, such as inhalation treatment, used in cases of chronic obstructive pulmonary disease (COPD) in the present study ($n = 3480/6000$)

Treatments	Proportion in COPD group as a whole, *n*(%)	Proportion in inhalation treatment only, *n* (%)	χ^2 and *p*
Levosalbutamol monotherapy	1860 (31.0)	1860 (53.4)	$\chi^2 = 759.31$ $p < 0.00001$
Levosalbutamol plus beclometasone	1080 (18.0)	1080 (31.0)	
Formoterol plus budesonide/salmeterol plus fluticasone with or without tiotropium (Difficult treatment)	540 (9.0)	540 (15.5)	

3.2 | Core observations

We have observed that 3% of study cases were aware of their illness as COPD, 54% were not having knowledge about COPD, and 43% cases were not accepting the COPD diagnosis ($p < 0.0001$). Inhalation treatment use was documented in 58% of COPD cases, with 31% cases of levosalbutamol monotherapy, 18% cases of levosalbutamol plus beclometasone, and 9% cases of either formoterol plus budesonide or salmeterol plus fluticasone ($p < 0.0001$) (Table 2). Oral medicines use was documented in 42% of COPD cases, with 16% cases of

TABLE 3 Oral treatment method used in cases of chronic obstructive pulmonary disease (COPD) ($n = 2520/6000$)

Treatments	Proportion in COPD group as a whole, *n* (%)	Proportion in Oral treatment only, *n* (%)	χ^2 and *p*
Theophylline	960 (16.0)	960 (38.1)	$\chi^2 = 343.63$ $p < 0.00001$
Salbutamol	420 (7.0)	420 (16.7)	
Oral steroids	1140 (19.0)	1140 (45.2)	

theophylline, 7% cases of salbutamol, and 19% cases of oral steroids ($p < 0.0001$) (Table 3). Totally 43% of study cases were difficult to accept labeled as "Difficult patients," and 91% of cases didn't receive rational inhalation treatment and were labeled as "Difficult treatment" and 42% cases were treated with oral medicines over rational inhalation treatment by physicians and labeled as "Difficult doctor."

4 | DISCUSSION

4.1 | Prevalence of awareness of COPD in rural settings attending tertiary care hospital

This study was conducted in a peripheral part of India with a predominantly rural population and the literacy rate was observed in 60% of cases with gender correction. COPD awareness was observed in 3% of cases only and cases disclosed that they acquired knowledge about COPD from digital media. Ghorpade et al.[13] conducted a study in urban slums and rural settings in India and observed awareness about COPD in 1% of the population. Other studies have reported awareness rates of 49% in Turkey,[14] 21% in Japan,[15] 17% in Spain,[16] 8% in France,[17] 17% in Canada,[18] 4% in Brazil, 1910% in Germany, 19% and 1% in Korea.[19] Our study data and study by Ghorpade et al.[13] give a clear statement as the Indian rural population is least aware of COPD. Lack of knowledge regarding the disease, less awareness about treatment options, and absence of use of spirometry by family physicians were the hurdles for less awareness about COPD in the community. Zielinski et al.[20] observed a 42% increase in COPD diagnosis with spirometry in symptomatic cases. Buffels et al.[21] analyzed the usefulness of spirometry performed by general practitioners in the early diagnosis of COPD. Proper training regarding the methodology of spirometry has shown a significant impact on appropriate diagnosis and decreasing the risk of overdiagnosis and underestimation of COPD. Eaton et al.,[22] Schermer et al.,[23] and Enright et al.[24] mentioned similar observations and recommended proper training in spirometry and standard methodology to meet acceptability and reproducibility criteria. Mannino et al.,[25] in their largest population-based survey in the United States National Health and Nutrition Examination Survey, found that less than half of cases with COPD receive actual physician diagnosis, which is similar tour findings. Studies[26–29] have documented an increased global prevalence of COPD due to increased tobacco consumption which is equally associated with underdiagnosis and undertreatment.

4.2 | Types of inhalation treatments prescribed for COPD in rural settings attending tertiary care hospital

As per our study, the high cost of long-acting or rational inhalation treatments and improper drug selection by family physicians was the reason for the least preference for inhalation medicines over oral medicines. Globally, the Inhalation treatment method is the preferred route of administration of drugs for treatment of COPD and is considered as "lung targeted therapy" and evidence-based medicine has observed significant improvement in symptom control and lesser systemic side effects due to the smaller volume of drug used as compared to the oral or intravenous route of administration.[30] Similarly, various studies[31,32] have mentioned COPD management remains suboptimal due to lack of knowledge or unawareness regarding current guidelines by treating physicians, and poor adherence by patients to prescribed medicines regarding the usefulness of rational inhalation treatment. Foster et al.[32] observed different preferences of drugs by primary care physicians during the treatment of COPD. They also reported a selective preference for long-acting beta-agonists (salmeterol or formoterol) in 35% of cases of COPD which is very much higher than our study with a preference in 9% cases only.[32] Numerous authors in their studies[33–36] mentioned the "cost factor" as a major driving factor during rational inhalation treatment. The authors also mentioned that higher cost is the reason for the underuse of long-acting beta-agonist combinations with inhaled corticosteroids over short-acting drug combinations. Authors[37–39] in their studies have reported the beneficial role of tiotropium in COPD cases in decreasing hospitalizations due to exacerbations and helping in decreasing financial burden due to exacerbation, and satisfactory improvement in symptom control without an increase in the overall cost of treatment. Indian guidelines recommended Inhalation treatment as the rational therapy in the management of COPD.[40]

4.3 | Oral treatment prescribed for COPD in rural settings attending tertiary care hospital

In the present study, more frequent use of oral medicines for the treatment of COPD disease was observed due to a

lack of awareness regarding the lesser benefit of oral medicines by patients and doctors and the cost-effectiveness of oral medicines over inhalation treatment. Authors[41–44] have reported similar preferences and trends of the use of oral medicines over inhalation treatment as the former are cheaper, easily available, and simple to use and the latter is costlier, requires specialist/pulmonologist consultation, and requires training before use. They also mentioned similar to our study transient symptom control with oral medicines is one of the "disease control criteria" which can be achieved with oral medicines, although the long-term benefits of these medicines are not known or not expected by patients.[41–44] GOLD guidelines[2] and Indian guidelines[40] also recommended against the use of oral medicines in COPD unless the patient is unaffordable and or inhaled medicines are not available.

4.4 | Beliefs, experiences, and behaviors observed during the study as difficult treatment, difficult patient, difficult doctor

We have recorded surprising beliefs, experiences, and behaviors by COPD cases in "treatment preferences" to oral medicines over rational inhalation treatment. The most common misbelief is that inhalation will decrease lung strength and have to continue for the entire life without any gap. Other misbeliefs are that inhalation treatment options are equivalent to oxygen therapy and increase dependency for symptom control once started and they consider inhalation as the last resort to use in COPD. Some patients experienced minimal adverse events with inhalation as altered speech due to improper oral drug washout and manifested as phobia regarding loss of voice. Few COPD cases have documented urinary retention after tiotropium inhalation treatment which has been reflected as increased creatinine levels resulting in aversion to inhalation treatment. Some patients believe that inhaled medicines will weaken the respiratory tract and should be avoided as far as possible. All mentioned facts have resulted in oral preference over inhalation and are considered "difficult patients."

We have recorded in a present study that patients believe inhalation treatment is a higher strength treatment (longer-acting bronchodilators LABA-LAMA with inhaled corticosteroids) than oral treatment due to cost difference. Other misbeliefs in the category of inhalation treatment as longer-acting drugs are costlier than short-acting drugs and these are higher strength drugs and should be reserved for advanced courses of illness or when disease advances or health conditions worsen requiring hospitalizations. Some patients believe costlier inhalation treatment will have more side effects as documented with tremors and altered voice in comparison to cheaper oral drugs without these side effects. Importantly, patients experienced some relief with short-acting drugs which are cheaper although the benefit is not as much as long-acting drugs which are costlier, they consider symptomatic relief as a basic disease control parameter apart from long-term outcomes and benefits of long-term inhalation treatment. As per our study, the cost is the basic factor for more preference for oral medicines over inhalation treatment in the management of COPD and is considered a "Difficult treatment."

In our study, we have specifically documented more preference of treating physicians for oral medicines over rational inhalation treatment in COPD cases. The most common experience by treating physicians is cost-effective oral medicines, easy to use, and universal availability over inhalation treatment. Other experiences are specially mentioned by the majority of physicians such as they have experienced lost follow-up cases whenever offered inhalation treatment and those patients prescribed oral medicines showing adequate adherence irrespective of partial symptom control. They have mentioned that patients were demanding oral medicines over inhaled medicines. The most common misbelief was minimal symptom control achieved with oral medicines although transient and not as effective as inhalation treatment will be sufficient for their patients. Lack of knowledge regarding COPD disease and the usefulness of rational inhalation treatment they are preferring oral medicines over inhalation treatment and are reluctant to shift to inhalation after knowing the benefits and are regarded as "Difficult doctors."

4.5 | Other important observations from the present study

We have observed a heterogeneous cultural trend in rural settings and smoking is relatively less common as compared in the western world. Risk factor analysis documented that agricultural dust/pollution with or without biomass fuel exposure is a predominant risk factor for COPD. Eosinophilia in blood and sputum were additional treatment defining results observed and rational for more preference by medical experts in India to the combination inhalation with inhaled corticosteroids as LABA-ICS over LAMA-LABA as observed in the western world with neutrophilia in blood and sputum in COPD cases.

We have also observed that long-acting and short-acting inhalation drugs were used in 45% of cases in groups A and B and in 55% of cases in groups C and D, respectively. This diverse combination of inhalation use was documented due to preference by family physicians in rural settings and demand by patients as they believe only symptom control is a basic disease control parameter.

As per available scientific evidence, spirometry is the diagnostic test for COPD which will pick up COPD at an earlier stage. In the present study, 14.85% of cases were diagnosed with COPD with minimal symptoms and they are unaware of COPD, 65% of cases were having

moderate to severe airflow obstruction and had a history of hospitalization due to exacerbations in the recent past. Still, the majority of these cases are not on rational inhalation treatment.

In the present study, COPD cases with zero to one exacerbation without hospitalization were 41.15% cases (2469/6000) and >2 exacerbations or >1 required hospitalization were 58.85% (3531/6000). Interestingly, more than half of the COPD cases were having either one or more exacerbations and were never honored with rational inhalation treatment combinations of LABA-ICS and or LAMA.

4.6 | The issue needs further analysis and will have an impact on diagnosis and treatment of COPD: Recommendations

More disease awareness regarding the use of spirometry in peripheral or rural settings through digital or social media and more emphasis on spirometry and rational inhalation treatment is needed.

Spirometry training campaigns on regular intervals by medical schools, medical experts, and pulmonologists are conducted to train and involve general physicians/family physicians or primary health care providers.

Rational treatment awareness by Government organizations and medical experts using social or digital media with attractive and view-changing "slogans" such as:

Inhalers are right choice for COPD

Inhalers will control disease progression

Inhalers will decrease risk of hospitalization and overall cost of care in comparison to cost of rational inhalation medicines

Inhalers are safe to use for longer duration and for entire life without any side effects

Inhalers can be used in all age groups; inhalers' dose is less than oral medicines and ultimately lesser side effects

Inhalers should be taken after consultation with lung experts; Inhalers will prevent "lung attack" or exacerbations

5 | CONCLUSION

"Doctor–patient–drug trio" discordance clubbed as "difficult doctor, difficult patient, and difficult treatment" is a very common issue observed during diagnosis and management of COPD in peripheral settings in India.

We "hope" and recommend the use of spirometry tests as a routine in all chronic respiratory symptoms patients for exact diagnosis of COPD and more emphasis should be given to the training of family physicians in spirometry. Oral medicines are commonly preferred treatments in COPD over universally accepted inhalation treatment due to misbeliefs, experiences, and behaviors of patients and doctors.

Now or when to "hype" for more awareness and sensitization regarding the benefits of rational inhalation treatment in COPD, especially advantages of these methods of treatment in symptom control, improvement in quality of life and long-term disease-related outcomes, and special emphasis on their role in decreasing hospitalization risk during exacerbation and overall cost of treatment.

AUTHOR CONTRIBUTIONS

All authors contributed equally during the complete study duration, Respiratory questionnaire (RQCOPD) preparation, data collection, data analysis, manuscript writing, manuscript edition, and final version of the present manuscript.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

All data generated or analyzed during this study are included in this published article. The data sets generated during and/or analyzed during the current study are not publicly available due to our author policy and in case, if required, will be made available from the corresponding author on reasonable request. All study materials submitted and analyzed in this manuscript can be made publicly available as per journal policy.

ETHICS STATEMENT

This study was approved by the Institutional Review Board/Ethics Committee of MIMSR Medical college, Venkatesh chest Hospital and Critical Care Center, Latur, India (approval # VCC/28-2016-2017; approval date 06/07/2016).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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