



**Assessment of prescribing pattern of bronchodilators among
adult patient in pulmonology Department of tertiary care Hospital,
Bengaluru**

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ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is characterized by progressive airflow limitation which is not fully reversible but it is preventable and treatable. Bronchodilators are used as first line agent for treatment of COPD.

Aim: To assess the prescribing pattern of bronchodilators among the adult patients with Chronic obstructive pulmonary disease in pulmonology department.

Method: A six month prospective observational study was conducted in pulmonology department of Tertiary care hospital in Bengaluru. Data demographics and medication was collected and prescribing pattern was compared with GOLD guidelines.

Result: There are 73 patients were recruited for a study from department of pulmonology. As the study is based on prescription pattern of bronchodilators we assessed the prescription data of these 73 patients. Out of 73 patients there were 43 males (58.9%) and 30 females (41.1%) were affected by COPD and the most comorbidity was found to be diabetes mellitus and hypertension. The most prescribed bronchodilator was Levosalbutamol (53.1%) followed by Acebrophylline (30.8%). And the dose prescribed was 0.31, 0.63, 1.2 mg and 100mg. In this study bronchodilators prescribed was compared with Global Initiative for Obstructive Lung Disease guidelines.

Conclusion: Levosalbutamol was prescribed frequently among bronchodilators to treat the inpatient or hospitalized patient with COPD. However all bronchodilators were prescribed according to the GOLD guidelines.

Key words: Chronic obstructive pulmonary disease (COPD), bronchodilators, corticosteroids, Global Initiative for Obstructive Lung Disease guidelines (GOLD), Prescription pattern.

INTRODUCTION:

Respiratory diseases are the type of diseases, which affects the lungs and other parts of

respiratory system. It is classified as upper respiratory tract infection (URTI) and lower respiratory tract infection (LRTI) based on the location of the disease. Upper respiratory tract infections are the illness caused by the acute infection in the upper part of respiratory system which is nose, sinus, pharynx or larynx. It includes common cold, pharyngitis, laryngitis, sinusitis, tonsillitis etc..

Lower respiratory tract infections are the infection in the lower part of respiratory system, it includes various diseases like COPD, asthma, bronchitis, pneumonia, bronchiolitis etc.

Chronic obstructive pulmonary disease (COPD) is characterized by progressive airflow limitation which is not fully reversible. It is a chronic and progressive disease, associated with abnormal inflammatory response of lungs to noxious particle or gases.

Includes two principle conditions

- ✓ Chronic bronchitis
- ✓ Emphysema
- Chronic bronchitis is a condition of excess mucus secretion with cough for at least a period of 3 months in 2 consecutive years.
- Emphysema is a condition of abnormal and permanent enlargement of the airspaces in lungs and causing destruction of their walls without fibrosis Cigarette smoking is the most common risk factor and accounts for 85% - 90% of COPD cases.

Other causes includes chemical vapors, irritants, fumes, dust like silica dust, cotton dust or grain dust and other occupational dust such substances in gold or coal mining. It also includes air pollution. Host factors include genetic causes; the hereditary deficiency of $\alpha 1$ antitrypsin (AAT) can also cause development of emphysema and pulmonary dysfunction. Other host factor includes airway hyper responsiveness and lung growth.

In order to standardize the care of patients with COPD and present evidence based recommendations, the national heart, lung and blood institute(NHLBI) and the world health organization (WHO) launched the global initiative for chronic lung disease(GOLD) in 2001.It has strategy for the diagnosis, management and prevention of COPD.

According to GOLD guidelines, the non-pharmacotherapy for COPD includes smoking cessation, vaccination. As smoking is one of the major causes in COPD, smoking cessation is important in the treatment of COPD, nicotine products can be used for smoking cessation. Influenza vaccination can reduce lower respiratory infections. Different classes of medications can be used in pharmacotherapy of COPD as per gold guidelines which includes,

- ✓ Bronchodilators
- ✓ Corticosteroids
- ✓ Mucolytic agents
- ✓ Antibiotics
- ✓ Anti-inflammatory agents

Bronchodilators are used as the first line drugs for the treatment of COPD. It is used to relieve symptoms like dyspnea, improve exercise capacity and decrease air trapping in lungs. It can be used as single drug or combined with other drugs like corticosteroids for the treatment of COPD. Bronchodilator are classified into different classes such as short and long acting bronchodilator, short and long anti muscarinic agent and methyl xanthine's.

Bronchodilator classified into Beta 2 agonist, muscarinic antagonist and methyl xanthine's.

- ✓ In beta 2 agonist there are two types of bronchodilators short acting beta 2 agonists and long acting beta 2 agonist (LABA).
- ✓ In muscarinic antagonist there are two types short acting muscarinic antagonist (SAMA) and long acting muscarinic antagonist (LAMA).
- Short acting beta 2 agonist (SABA) includes such as salbutamol (albuterol), levalbuterol, terbutaline and fenoterol.
- Long acting beta 2 agonist (LABA) includes such as salmeterol, olodaterol, formoterol, indacaterol, and arformoterol.
- Short acting muscarinic antagonist (SAMA) includes such as ipratropium bromide and oxitropium bromide.
- Long acting muscarinic antagonist (LAMA) includes such as tiotropium bromide, aclidinium bromide, glycopyrronium bromide, umeclidinium, glycopyrrolate and revefenacin.
- ✓ Methylxanthines includes such as aminophylline, theophylline and doxofylline.

Aim and Objective:

- To assess the prescribing pattern of bronchodilators among the adult patients with chronic obstructive pulmonary disease in pulmonology department.

Objectives of the study

Primary Objectives:

- To assess the rationality of bronchodilators prescribed to patient as a management for Chronic Obstructive pulmonary disease in Pulmonology department by using GOLD guidelines.

Secondary Objectives:

- To assess potential drug-interaction and adverse drug reaction among bronchodilators prescribed to the adult patient with chronic obstructive pulmonary disease.

METHODOLOGY:

Study site:

- The proposed study will be carried out in the pulmonology department of tertiary care Hospital, Bengaluru.

Study Design:

- The proposed study is prospective observational study.

Study Duration:

- The proposed study will be carried out for a period of 6 months.

Study Subjects:

- Total number of subjects/patients enrolled into the study: 73.

Study Criteria:

Inclusion Criteria:

- The in-patients of either sex or aged above 18 years to 60 years.
- The in-patient who are diagnosed with chronic obstructive pulmonary disease

and admitted in pulmonology department.

- The in-patients who are prescribed with bronchodilators in COPD patients.

Exclusion Criteria:

- The in-patients who are below 18 years old and above 60 years.

The in-patients who are diagnosed other than COPD who admitted in pulmonology department

Status of Human Ethical Clearance:

The proposed study was initiated after the institutional human ethical committee from tertiary care hospital, Bengaluru.

Study Procedure:

- Step 1: All in patients with COPD from pulmonology department who satisfy in inclusion criteria are considered for the study.
- Step 2: The demographics, medication and clinical data are documented into the patient data collection form.
- Step 3: From the documented data prescription pattern is assessed based on GOLD guidelines.
- Step 4: In addition the adverse drug reaction and potential drug drug interaction are identified among the medication using lexicomp drug database.
- Step 5: Results will be subjected to statistical analysis.

Variables that are estimated in the study:

- Age of the enrolled patient
- Medications prescribed to enrolled patients

Statistical Analysis:

- Descriptive statistics will be performed. All the data will be analyzed by using Microsoft excel.
- Based on cases enrolled for one week, 2 patients with COPD out of 20 patients in the pulmonology department were prescribed with bronchodilator.
- Hence from the following formula sample size was calculated to be 73.

Study Benefit to Patient and Society:

The participation of the patients will help to bring the rational drug use and appropriateness of the prescription, but no direct benefit will be achieved to the patients.

Study Risk and Discomfort:

- The collection of data from prescriptions might involve sharing of sensitive information like patient personal and clinical data. If patient feel uncomfortable with the process, then they can deny the data collection from the prescription.
- There is no significant risk involved in your participation as we only collect data specific to our study.

RESULT:

73 patients were recruited for a study from department of pulmonology. Out of 73 patients there were 43 males (58.9%) and 30 females (41.1%) patients were affected by COPD. Majority of patients were from age group between 50 -60 years. When 73 patients assessed

for social habits there were 38 patients had a habit of smoking and 17 patients were alcoholic. On medication chart review of 73 patients, bronchodilators were most prescribed drugs. Among brands of bronchodilator levolin is the most preferred brand of drug and corticosteroid was second choice of drugs for treating COPD patients. In our study 30 patients received combination of levosalbutamol + acebrophylline as the most preferred, which is been given in the form of respules through nebulizer. During the study drug- drug interactions and adverse drug reaction was not reported in our study population. During the study drug- drug interactions and adverse drug reaction was not reported in our study population. When the compared the prescription of 73 patients with GOLD guidelines for maintenance therapy, the prescription were accurately followed as in GOLD guidelines.

DEMOGRAPHIC DATA:

Age wise distribution:

For the study the patients were recruited between age group of 21 - 60 years, In which majority of the patients for from age category 50 -60 years. Below table shows age wise distribution of this disease.

Age group	No. Of Patients	Percentage
21-30	2	2.7%
31-40	5	6.9%
41-50	7	9.6%
51-60	59	80.8%
Total	73	100%

Table 1: Age wise distribution

Gender wise distribution:

Among 73 patients recruited 43 male(58.9%) patients with the mean age of 54.6 years and 30 female(41.1%) patients with the mean age of 53.3 years were affected by COPD.

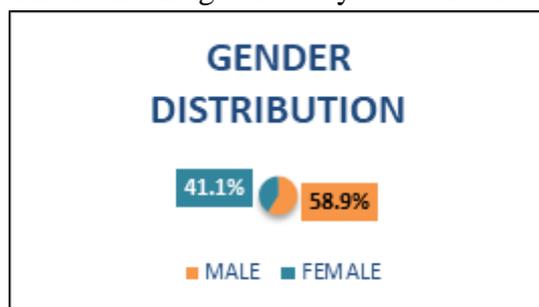


Figure 1: Gender distribution

Social habits distribution:

On assessing patient's data for social habits it is assessed that 38 patients had habit of smoking and 17 patients were alcoholic.

SOCIAL HABITS	NUMBER OF PATIENTS	PERCENTAGE
Alcoholic	17	23.3
Non Alcoholic	56	76.7
Total	73	100

Table 2: Percentage of Alcoholic and Non-alcoholic Patients

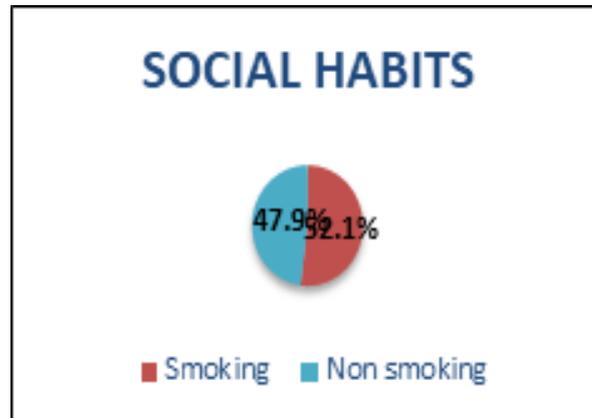


Figure 2: Graphical representation of Alcoholic and Non-alcoholic patients

Comorbid distribution:

On assessing patient's data for comorbidities it is assessed that 38 patients has comorbidities mostly with diabetes mellitus, hypertension and ischemic heart disease and 35 patients were free from comorbid conditions.

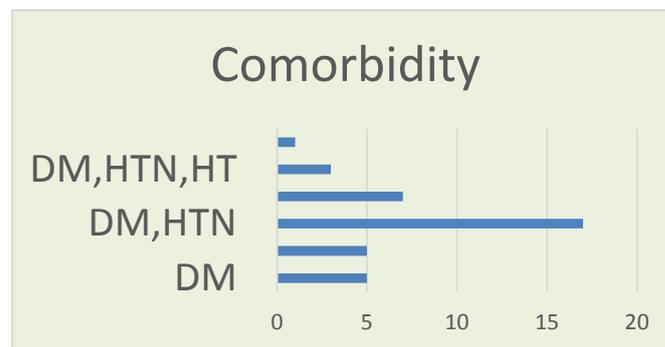


Figure 3: Graphical representation of Comorbid conditions

MEDICATION DATA:

On assessing prescription pattern for 73 patients it shows total of 130 bronchodilators were prescribed with the generic of levosalbutamol (53.1%) which is the most prescribed bronchodilator followed by acebrophylline (30.8%), ipratropium bromide (10.8%), foracort(2.3%), duolin(2.3%) and ortivin nasal Spray (0.7%).

Brand name	Generic name	No. Of Rx	%
Levolin	Levosalbutamol	69	53.1
Foracort	Formoterol+budesonide	3	2.3
Abphylline	Acebrophylline	40	30.8
Ipravent	Ipratropium bromide	14	10.8
Otrivin	Ipratropium bromide+Xylometazoline hydrochloride	1	0.7
Duolin	Salbutamol+Ipratropium bromide	3	2.3
	Total	130	100

Table 3: percentage of class of medication prescribed to the patients

Corticosteroids were second most prescribed class of drugs; about 60 drugs were prescribed in 73 patients which include methyl prednisolone (86.8%), budesonide (5%), prednisolone (3.3%), fluticasone (3.3%) and hydrocortisone (1.6%).

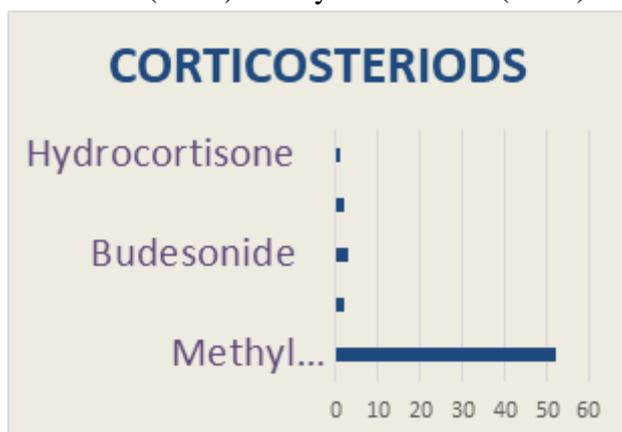


Figure 4: graphical representation of corticosteroids prescribed to the patients

Drug combination distribution:

Different treatment options were used for treatment of COPD among that dual combination therapy (56.2%) was preferred in most of the patients followed by mono-therapy (32.9%) and triple combination therapy (10.9%).

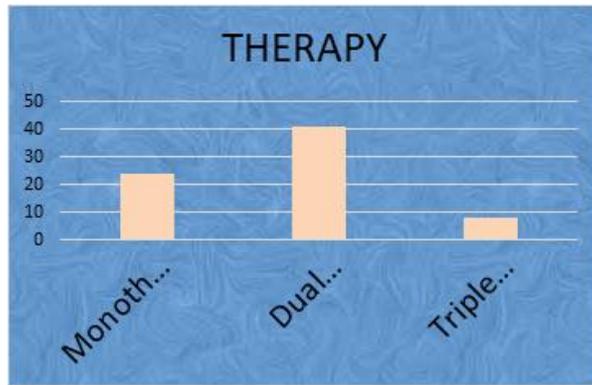


Figure 5: Graphical representation of drug combination prescribed to patients

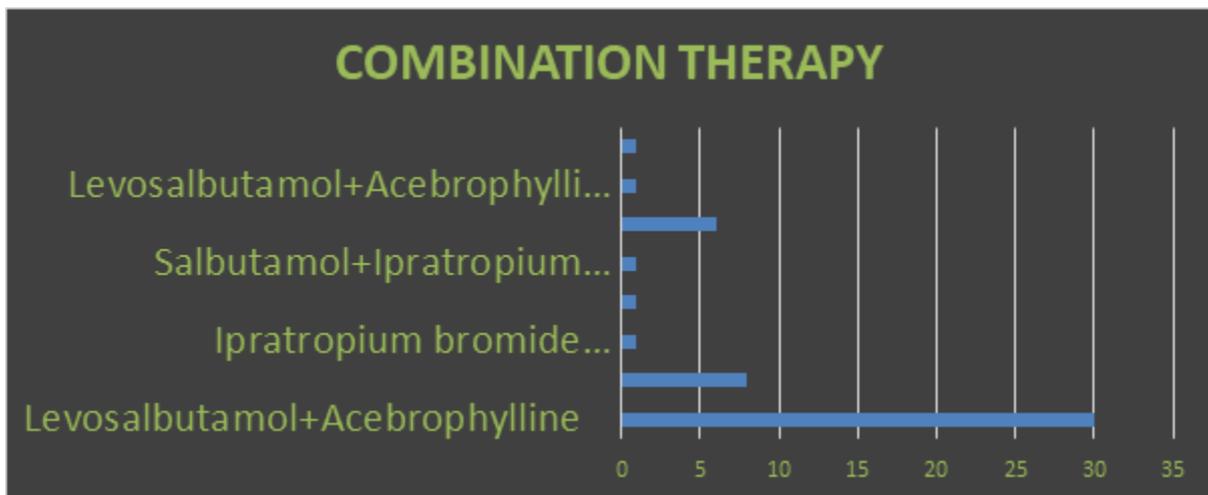


Figure 6: Graphical representation of combined drug therapy

In combination therapy different combination of drugs was used to treatment of people with COPD.

Route of administration:

In 73 recruited patients, Oral inhalation route was most preferred route of administration.

ROUTE OF ADMINISTRATION	NUMBER OF DRUGS	PERCENTAGE
Oral inhalation	89	68.5
Oral	40	30.7
Nasal	1	0.8
Total	130	100

Table 4: percentage of route of administration of drug to patients

Doses Administered to Patient's:

In 73 recruited patients, different doses of drugs were used, levosalbutamol was prescribed with 3 different doses, and other drugs were prescribed in only one dose.

DRUGS	DOSE	NUMBER OF DRUGS	PERCENTAGE
Levosalbutamol	1.2mg	14	10.8
Levosalbutamol	0.63mg	54	41.5
Levosalbutamol	0.31mg	1	0.8
Ipratropium bromide	0.5mg	15	11.5
Acebrophylline	100mg	40	30.8
Duolin	0.63mg	3	2.3
Foracort	200mcg	3	2.3
Total		130	100

Table 5: percentage of different doses administered to patients

In 73 recruited patients, prescribed drugs were used in different frequencies such as Q2hr, Q4hr, Q6hr, Q8hr, and Q12hr.

DRUGS	FRQUENCY	NUMBER OF DRUGS	PERCENTAGE
Levosalbutamol	Q8hr	38	29.2
	Q6hr	28	21.5
	Q2hr	3	2.3
Ipratropium bromide	Q8hr	6	4.6
	Q6hr	4	3.1
	Q12hr	2	1.5
	Q4hr	2	1.6
	Q2hr	1	0.75
Duolin	Q8hr	3	2.3
Foracort	Q12hr	2	1.6
	Q8hr	1	0.75
Acebrophylline	Q12hr	40	30.8
Total		130	100

Table 6: percentage of frequency of administration of drugs

Rationality in accordance to guidelines used:

As per GOLD guidelines, hospitalized patients were treated with maintenance therapy, which includes short acting bronchodilators as mono-therapy, two short acting bronchodilator as combination therapy and long acting beta 2 agonist + inhaled corticosteroid as combination therapy. Methy-xanthines used as additive therapy along with other treatment option. All the drugs used in treatment of COPD were in accordance to GOLD guidelines so the prescription pattern of the COPD patients was found to be rational.

DRUGS	COMPLIANCE WITH GOLD GUIDELINES	NUMBER OF PATIENT TAKING DRUGS	PERCENTAGE
Short acting bronchodilators			
Levosalbutamol	yes	69	53.1
Ipratropium bromide	yes	15	11.5
Methyl xanthines			
Acebrophylline	yes	40	30.8
Combination therapy SABA + SAMA			
Salbutamol + Ipratropium bromide	yes	3	2.3
Long acting bronchodilators + Inhaled corticosteroids			
Formoterol + budesonide	yes	3	2.3
Total		130	100

Table 7: Percentage of rationality of drugs prescribed in accordance to GOLD guidelines

DISCUSSION:

GOLD guidelines are a global strategy, which is developed for diagnosing, management, treatment and prevention of COPD. It is implemented by national heart, lung and blood institute and world health organization. It is used all over the world for appropriate treatment for patients with COPD. Arterial blood gas and spirometer tests were used in diagnosis of our study as per GOLD guidelines.

In our study the prescription pattern of bronchodilators was compared with GOLD guidelines. Bronchodilators such as levosalbutamol (levalbuterol), salbutamol (albuterol), ipratropium bromide, formoterol were prescribed according to GOLD guidelines. In that levosalbutamol and salbutamol is short acting beta 2 agonist, ipratropium bromide is a short

acting anticholinergic and formoterol is a long acting beta 2 agonist which is used as maintenance therapy for COPD patient as per GOLD guidelines. Acebrophylline is one of the methyl xanthine's derivatives which are also used for treatment of COPD. Doses of the drug are prescribed according to GOLD guidelines. Beta 2 agonist and anticholinergic are prescribed as nebulizer and given through oral inhalation route, acebrophylline prescribed as pills through oral route as per GOLD guidelines.

Prescription of 73 recruited patients were collected and assessed for different drugs of bronchodilators it shows levosalbutamol (levalbuterol), salbutamol(albuterol), ipratropium bromide, formoterol and acebrophylline are prescribed bronchodilators in our study. In which levosalbutamol (53.1%) is most prescribed bronchodilator followed by acebrophylline (30.8%), ipratropium bromide(11.5%), salbutamol(2.3%) and formoterol(2.3%). According to our study beta 2 agonist(57.7%) was most prescribed, followed by methyl xanthine's (30.8%) and anticholinergic (11.5%) is different from the study conducted by Aiswarya AV et al as their study focused on prescription pattern of COPD which includes different class of drugs prescribed in the treatment but we focused more on bronchodilators in our study. Different treatment options were used in our study levosalbutamol(31.5%), formoterol(1.3%), levosalbutamol + acebrophylline (41.1%), levosalbutamol + ipratropium bromide (11%) , ipratropium bromide + acebrophylline (1.3%), levosalbutamol + ipratropium bromide + acebrophylline (9.5%), salbutamol + ipratropium bromide + acebrophylline(1.4%) , salbutamol + ipratropium bromide + formoterol + budesonide (1.3%) , levosalbutamol + acebrophylline + formoterol (1.3%) is similar to the study conducted by Aiswarya AV et al as they also have used treatment options in there study.

CONCLUSION:

The study conducted by kempegowda institute of medical science in Bangalore shows the prevalence of COPD was 4.26%. Prevalance among males were 5.32% and females were 3.41%. According to the Karnataka disease burden profile. In top 15 causes of disease and death in 2016, COPD has the second place. Increasing age and rising air pollution in Bengaluru is causing a rise of COPD cases in the city. Lots of study was carried out for the management and treatment of COPD patients. In most of the studies prescription pattern of different class of drugs which is used in the treatment of COPD was studied. Our study particularly focused on the bronchodilators as it is used as first line drugs and drug of choice for the treatment of COPD according to GOLD guidelines. The study concludes that incidence of COPD was more common in males compared to females and between 50 - 60 years age group was most affected population. Smoking is one of the major causes of COPD in our study. Comorbid conditions were seen in most of the patients in that diabetes mellitus and hypertension were most common comorbidity. Bronchodilators were most prescribed class of drugs for the treatment of COPD in that the usage of short acting beta 2 agonist was found to be high in our study. From the assessment of prescription data of 73 patients, it concludes that the levosalbutamol was prescribed frequently in the hospitalized patients. Combination therapy of bronchodilators was preferred over mono-therapy in which combination levosalbutamol + acebrophylline was prescribed in most of the patients. These drugs are prescribed in the hospitalized patients as maintenance therapy which is in

accordance GOLD guidelines. Oral inhalation route is preferred route of administration. During the study drug- drug interactions and adverse drug reaction was not reported in our study population. All the prescribed drugs under the class of bronchodilators were rational and prescribed as per GOLD guidelines.

Authors Contributions

All the authors contributed equally in design of the work, acquisition and interpretation of data, and manuscript preparation, all authors have read and approved the manuscript.

Conflict of Interest

There is no conflict of interest from all the authors.

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Data Availability Statement:

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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