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**Original Research Paper** 

Pharmacology

# DRUG UTILIZATION PATTERNS IN PATIENTS WITH ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE AT TERTIARY CARE HOSPITAL

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Chronic obstructive pulmonary disease (COPD) has a worldwide prevalence of 10% and is among the ABSTRACT first four causes of global mortality. 3-16% of patients with exacerbation must be hospitalized. Objectives of study are Primary objectiv; Evaluation of drug utilization patterns in patient with acute exacerbation of COPD in tertiary care hospital and Secondary objective: To correlate association of chronic obstructive pulmonary Disease with demographic details of patients, To assess the prescribing pattern of standard drugs in patients with exacerbation of chronic obstructive pulmonary Disease and To assess the health related quality of life (HRQOL) of the patients. The study was conducted at Mallige Hospital. Mallige Hospital is a multispecialty tertiary care hospital with over 126 beds, conveniently located in the heart of Bangalore. The study was conducted in the Inpatient deportment of the Hospital. A Hospital based prospective observational study was conducted. The study was done for six months with data collection duration for three months. Study population include patients admitted in Inpatient deportment of the Hospital. Inclusion criteria: Patients who are diagnosed as suffering from chronic obstructive pulmonary disease along with co-morbidities and who visited the hospital for acute exacerbation of the disease was included using diagnostic criteria such as ICD-10. Admitted for acute exacerbation of COPD of various étiologies and with or without co morbidities. Exclusion criteria: Patients in the IP ward admitted with diagnosis of COPD who are not willing to participate in the study. Patients who are admitted in comatose and unconscious condition and in an aggressive treatments. Patients who are under other chronic steroid use conditions. Prescriptions from pregnant women and with insufficient data are excluded. Out of 110 patients included in the study, 26 (23.63%) were females and 84 (76.36%) were males. majority 53 (48.18%) of them were found in the age group between 41-60 years, followed by 42 (38.18%) in the age group between 61-80 years, 11 (10%) in the age group between 18-40 years, then 4 (3.63%) were found between 61-80. Among 206 drugs prescribed for COPD patients 3 drugs were inappropriately prescribed. It was observed that Hypertension 66 (29.07%) followed by Diabetes mellitus 45 (19.82%), and Anemia in 32 (14.09%). Majority of the patients were of a low socioeconomic status. Most of the patients came under Types I and II grade of exacerbation (61.81% and 29.09%, respectively) as per the grading scale for exacerbation of COPD. This result showed tendency of polypharmacy with maximum number of prescriptions were having 6 drugs (37.2%). Intravenous were the major formulations used for administration of drugs in this study (36.98%). The present study represents the current prescribing trend for anti COPD agents. Despite the use of drugs according to the availability and physician's preference, it was found in the analysis that majority were in accordance with GOLD criteria recommendations. Most of the patients were only taking the medications offered at the hospital, and not buying the drugs from outside pharmacies, which were unavailable in the hospital. By including these drugs in the central purchase committee list of government, the treatment can be more effective and economy. Several guidelines have been developed worldwide for the management of exacerbation of chronic obstructive pulmonary disease, and these serve as reference standards for clinical practitioners. However, many clinicians practice their own prescribing pattern in treating COPD patients according to their clinical experience. Primary care physicians need to be empowered in appropriate and evidence-based management of exacerbation of COPD. A review of these prescribing patterns and guideline-based use of anti-COPD medications can give better insights into the concept of personalized, yet cost-effective pharmacological management of COPD.

# KEYWORDS : COPD, FEA1, Chronic, HRQOL, HADS, Exacerbation.

### I. INTRODUCTION

Chronic obstructive pulmonary disease (COPD) has a worldwide prevalence of 10% and is among the first four causes of global mortality. In the United States, it affects 14.2 million people and 1.5 million annual visits to the doctor are registered for exacerbation.1 In India, it is the 3rd leading cause of death and contributes a significant and growing percentage of COPD mortality which is estimated to be amongst the highest in the world; more than 64.7 estimated age standardized death rate per 100,000 amongst both sexes.<sup>2</sup> According to the analysis report of the 'Indian Study on Epidemiology of Asthma, Respiratory Symptoms and Chronic Bronchitis in Adults' (INSEARCH) Phase I and II analysis, the prevalence of COPD in India were estimated to be 3.67%. The study population had rural and urban representation of both genders and the gender distribution shows that the prevalence in males and females was 4.46% and 2.86%

respectively. COPD possess an enormous burden in terms of morbidity, mortality, direct and indirect costs.11 3-16% of patients with exacerbation must be hospitalized. The mortality rate is close to 10%. The exacerbation of COPD produces loss of lung function, disease progression, increased morbidity and mortality, increased economic costs due to admissions to the Emergency Services and hospitalization.<sup>45</sup> The exacerbation of COPD is defined as an acute episode in the course of the disease, characterized by a worsening of the patient's symptoms, beyond the normal dayto-day variations, for which a change in medication is necessary.<sup>1</sup> 70% of the cases are secondary to an infectious process, 40-50% of bacterial origin, 30-40 viral and 10-20% mixed. In one third of patients, the cause of the exacerbation cannot be clearly identified (Table 1).<sup>5-6</sup> there is a complex interaction of multiple factors, including:

The type of infectious agent.

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- The environment (tobacco, occupational exposure).
- The host and its comorbidities (congestive heart failure, non-pulmonary infections, pulmonary embolism, pneumothorax, among others).

Bacteria and their toxins stimulate alveolar macrophages to produce harmful enzymes that affect the epithelium, produce mucosal hypersecretion, and generate pro-inflammatory cytokines that attract neutrophils. Viruses exhibit epithelial adhesion through intracellular adhesion molecules (ICAM-1); they also increase endothelin, a bronchoconstriction peptide, and increase oxidative stress. Neutrophils, tumour necrosis factor alpha, and CD8 + lymphocytes are the most important cells in inflammatory responses in exacerbated COPD. There is an increase in air obstruction, increased resistance, air trapping, greater work of breathing and oxygen consumption, worsening of the ventilation-perfusion ratio and deterioration of gas exchange.<sup>7</sup>

According to the ECLIPSE study (Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints, observational cohort), the main risk factors for hospital admission are: a history of exacerbations, severe airflow limitation, poor health, and age advanced, radiological demonstration of emphysema and a high leukocyte count.<sup>®</sup> Classification of COPD exacerbation according to the American Thoracic Society and the European Respiratory Society:<sup>§</sup>

- Mild: it can be controlled with an increase in the dose of the usual medication.
- Moderate: requires treatment with a corticosteroid or systemic antibiotic.
- Serious: needs assessment in the Emergency Department or hospitalization.

The diagnosis of COPD exacerbation is given by a worsening of symptoms; these include coughing, changes in sputum purulence or volume, wheezing, and dyspnoea.<sup>9</sup> Patients may present with altered state of consciousness, cyanosis, and increased anteroposterior diameter of the thorax, paradoxical abdominal movement, decreased breath sounds, wheezing and signs of right heart failure (oedema of the lower limbs, jugular venous distention).<sup>10</sup> In addition to a complete history and physical examination, basic laboratory tests, chest x-ray, and arterial blood gases should be ordered (Table 2).<sup>49</sup>

#### Arterial gases

They are indicated in the presence of moderate to severe respiratory distress, ambient oxygen saturation less than 92%, pH monitoring, oxygen partial pressure and carbon dioxide partial pressure.<sup>13</sup>

#### Chest x-ray

It should be considered routinely in patients with an exacerbation of COPD, especially in those who present with an exacerbation and to rule out other differential diagnoses such as pneumonia, pneumothorax or pulmonary oedema.<sup>13</sup>

#### Electrocardiogram

Mortality in COPD patients increases 58% due to cardiovascular diseases. The electrocardiogram is a fundamental part in the study of patients with exacerbation because it helps to diagnose cardiac arrhythmias and coronary disease.<sup>13</sup>

#### Gram and sputum culture

It should not be requested routinely, only in patients with persistent purulent expectoration who do not respond to initial empirical antibiotic treatment and in those with high suspicion of Pseudomonas aeruginosa.<sup>14</sup>

The administration of oxygen has important therapeutic

effects, which include a relief of pulmonary vasoconstriction, decrease in right overload, improvement in myocardial perfusion relieving ischemia (if present); It has a bronchodilator effect, improves the oxygenation of the respiratory muscle avoiding its exhaustion and relieves dyspnea by improving the tissue oxygenation of the patient.<sup>15</sup> The big fear is that uncontrolled oxygen use in COPD patients can cause (or worsen) hypercarbia. Some studies have observed an increase in pCO2 by freely correcting hypoxemia. Physiologically, the COPD patient does not control ventilation due to changes in pH in the respiratory centre. It is the partial pressure of oxygen measured in peripheral receptors. Thus, it indicates, ineffectively, the need for more or less ventilation. The carotid body is unable to control ventilation without hypoxemia. It suppresses its activity when the pO2 is greater than 60 mm Hg. This is the reason why Hb saturation should be kept around 90% or a pO2 between 55 and 60 mm Hg.<sup>16</sup>

Studies carried out in real conditions indicate that in most cases the ideal oxygen delivery system in COPD patients is the Venturi mask, which provides uniform oxygenation to the patient that does not vary with inspiratory volume and heart rate. It is possible to use a nasal cannula.<sup>17</sup> Bronchodilator therapy is the main medication as they relieve symptoms and improve bronchial obstruction. The use of a short-acting beta agonist (salbutamol or fenoterol) increases the concentration of cAMP in the bronchial muscle, producing bronchodilation. Additionally, the mucociliary escalator clearance is improved, it controls the cellular apoptosis of the PMN and the permeability of the capillaries decreases, producing relief in the patient. The anticholinergic (ipratropium), acts on the muscarinic receptor. In addition to reducing cholinergic tone, which is increased in COPD patients, it has a bronchodilator effect and muco-ciliary clearance.<sup>18</sup> Corticosteroids have shown benefit in patients with exacerbated COPD because they have reduced airflow limitation, failure rate, relapses, hospitalization time, and improved symptoms.<sup>19</sup> Oral use of antibiotics is preferable as they are just as effective as intravenous use, at a significantly lower cost. The COPD patient has bacterial colonization. In general, mild cases will have pneumococcus, haemophilus influenza and Moraxella catarrhalis as causative germs. Severe cases will have colonization by gram negative bacteria including pseudomonas, this is particularly valid for patients with a FEV 1 below 50%. This study optimized the drug use patterns and to extend the rationality to enhance patient health related quality of life (HRQOL) in acute exacerbation of COPD. The HRQOL (health related quality of life) questionnaire is a good indicator of the health status of COPD patients and HRQOL score can be determined and the success of therapy can be predicted.. Exacerbation frequency and smoking status significantly changed the HRQOL scores. Using multifactorial nonlinear regression analysis, a mathematical model was developed by which the scoring of the HRQOL questionnaire can be obtained in a simple and easy way using spirometry parameters, smoking habits, and exacerbation frequency during the period. The St. George's Respiratory Questionnaire (SGRQ), Modified Medical Research Council (mMRC) Dyspnea Scale, Hospital Anxiety and Depression Scale (HADS), and general health questionnaire (SF-36) are widely used HRQOL scales for chronic obstructive pulmonary disease. The concept of HRQOL is present in medical research to the extent that recent studies have revealed that the measurement of HRQOL is crucial for clinical trials Socioeconomic status (SES) is a live of economic and social science conditions of an individual's work expertise and of a personality's or families economic and social position in reference to different community members. Sometimes financial gain, education, and occupation are taken into consideration to work out socioeconomic status. In most of the scientific studies like hospital and community-based studies,

assessment of socioeconomic status of an individual/family is a very important pre-requisite as several diseases are directly or indirectly related to socioeconomic status. Socio-economic scales are captivated with analysis of financial gain and need to be updated with dynamical consumer index. Kuppuswamy socioeconomic scale is legendary among the researchers, students and public health personals, regular updating of this socioeconomic scale very important to maintaining its validity in assessing the socioeconomic standing and finding the socio-economic class of people and families while conducting community-based, hospital-based & social studies.<sup>22</sup> People belonging to the lower socioeconomic strata will have increased prevalence of COPD. To draw such a conclusion, firstly, we need to know the details of the distribution of the entire target population by socioeconomic status and then calculate prevalence rates for COPD in the different socioeconomic strata.23

# II. MATERIALS AND METHODS DURATION OF STUDY

The study was done for six months with data collection duration for three months.

### SITE OF STUDY

The study was conducted at Mallige Hospital. Mallige Hospital is a multispecialty tertiary care hospital with over 126 beds, conveniently located in the heart of Bangalore.

#### STUDY DESIGN

A Hospital based prospective observational study was conducted.

# SOURCES OF DATA AND MATERIALS

- Patient data collection from.
- Patient inform consent form.
- Stored from near patient.
- Patient case sheet.
- Spirometry Test results.
- Laboratory data reports.
- Prescription of patients.
- Questionnaires and discussion assessment.

# STUDY CRITERIA

# Inclusion criteria

- Patients who are diagnosed as suffering from chronic obstructive pulmonary disease along with comorbidities and who visited the hospital for acute exacerbation of the disease was included using diagnostic criteria such as ICD-10.
- Admitted for acute exacerbation of COPD of various etiologist and with or without comorbidities.

#### Exclusion criteria

- Patients in the IP ward admitted with diagnosis of COPD who are not willing to participate in the study.
- Patients who are admitted in comatose and unconscious condition and in an aggressive treatments.
- Patients who are under other chronic steroid use conditions.
- Prescriptions from pregnant women and with insufficient data are excluded.

#### STUDY PROCEDURE

Patients admitted in the inpatient ward with exacerbations of COPD was included in the study, by considering the inclusion and exclusion criteria. However, those patients who were not admitted in the hospital and who do not want to give consent to participate in this study were excluded. The purpose of the study were explained to the patient. The data collected was analyzed and interpreted to evaluate the objectives of the study.

#### STATISTICAL ANALYSIS

Statistical analysis was performed using MS-excel and the result was statistically analysed using appropriate statistical method.

#### III. RESULTS

This study was conducted for a period of 6 months, the study included 110 patients from IP department of Mallige Hospital, a tertiary care hospital in Bangalore.

#### PATIENT DISTRIBUTIONS BASED ON DEMOGRAPHIC DATA

Out of 110 patients included in the study, 26 (23.63%) were females and 84 (76.36%) were males. [Table 1, Figure 1]

#### Table 1: Patient Distribution Based on Gender

Gender	No of patients	Percentage
Male	84	76.36%
Female	26	23.63%
Total	110	100%



#### Fig 1: Patient Distribution Based on Gender

#### AGE DISTRIBUTION OF PATIENTS

Patients were categorized according to their age groups. Out of 110 patient's majority 53 (48.18%) of them were found in the age group between 41-60 years, followed by 42 (38.18%) in the age group between 61-80 years, 11 (10%) in the age group between 18-40 years, then 4 (3.63%) were found between 61-80. [Table 2, Figure 2.1 and 2.2]

#### Table2: Patient Distribution with Respect to their Age Groups

Āge	No. of Male	No. of Female	Total No. of
distribution in	Patients	Patients	Patients
years	(n=84)	(n=26)	(n=110)
18-40	8 (9.52%)	3 (11.53%)	11 (10%)
41-60	41 (48.8%)	12 (46.15%)	53 (48.18%)
61-80	33 (39.28%)	9 (34.61%)	42 (38.18%)
>80	2 (2.38%)	2 (7.69%)	4 (3.63%)



Fig 2.1: Graphical Representation of Patient Distribution with Respect to their Age Groups

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Fig 2.2: Graphical Representation of Patient Distribution with Respect to their Age Group

### DISTRIBUTION OF MEDICATION PRESCRIBED FOR ACUTE EXACERBATION OF COPD PATIENTS DURING HOSPITALIZATION

Among 206 drugs prescribed for COPD patients 3 drugs were inappropriately prescribed. The category of drugs like Antibiotic, Short acting beta-2 agonist, Anticholinergic agent and inhaled corticosteroids required more dosage adjustment when compared to other category of drugs. [Table 3, Figure 3]

# Table 3: Distribution of Medication Classes Prescribed for acute exacerbation of COPD $% \left( \mathcal{A}_{1}^{\prime}\right) =\left( \mathcal{A}_{1}^{\prime}\right) \left( \mathcal{A}_{2}^{\prime}\right) \left( \mathcal{A}_{2}$

Drug category	No. of patients (n=206)
Antibiotic	62 (30.09%)
Short acting beta-2 agonist	30 (14.56%)
Anticholinergic agent	27 (13.1%)
Inhaled corticosteroids	25 (12.13%)
Methylxanthines	22 (10.67%)
Corticosteroid	19 (9.22%)
Long acting beta-2 agonist	9 (4.36%)
Systemic corticosteroids	7 (3.39%)
Mucolytics	5 (2.42%)



Fig 3: Distribution of Medication Classes Prescribed for acute exacerbation of COPD

#### CO-MORBID CONDITIONS OF PATIENTS

Out of 110 patients enrolled in the study, it was observed that Hypertension 66 (29.07%) followed by Diabetes mellitus 45 (19.82%), and Anemia in 32 (14.09%). [Table 4, Figure 4.1 and 4.2]

Table 4: 0	Co-morbid	conditions of	f patients
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Co-morbid conditions	No. of Co- morbid (n=227)	Percentage
Hypertension	66	29.07%
Diabetes mellitus	45	19.82%

#### 4.4% alcoholism 10 29 12.77% coronary artery disease 1.76% Tuberculosis 4 12 5.28% Unstable angina Hyperlipidemia 12 5.28% 1.76% Liver dysfunction 4 32 14.09% Anemia 1.76% BPH 4 Thyroid Disorder 9 3.96%



Fig 4.1: Pie chart Representation of patient's Co-morbid conditions



Fig 4.2: Graphical Representation of patient's Co-morbid conditions

#### DISTRIBUTION OF TOTAL NUMBER OF CHARACTERISTICS

Majority of the patients were of a low socioeconomic status. Most of the patients came under Types I and II grade of exacerbation (61.81% and 29.09%, respectively) as per the grading scale for exacerbation of COPD. [Table 5, Figure 5.1 and 5.2 and 5.3]

### Table 5: Characteristics of the study population

No. of Patients	Percentage		
(n=110)			
conomic statues			
4	3.63%		
10	9.09%		
21	19.09%		
15	13.63%		
60	13.63%		
Severity index of lung function test			
72	65.45%		
21	19.09%		
17	15.45%		
Grade of exacerbation			
68	61.81%		
32	29.09%		
10	9.09%		
	No. of Patients (n=110)       conomic statues       4       10       21       15       60       ex of lung function t       72       21       17       of exacerbation       68       32       10		

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#### Fig 5.1: Characteristics of Socioeconomic statues



# Fig 5.2: Characteristics of Severity index of lung function test



#### Fig 5.3: Characteristics of Grade of exacerbation

# DISTRIBUTION OF TOTAL NUMBER OF DRUGS PRESCRIBED PER PATIENT

This result showed tendency of polypharmacy with maximum number of prescriptions were having 6 drugs (37.2%). [Table 6, Figure 6]

THERAPY PATTERN	NO. OF PATIENTS	IN PERCENTAGE
One drug	0	0%
Two drugs	1	0.9%
Three drugs	8	7.2%
Four drugs	9	8.1%
Five drugs	34	30.9%
Six drugs	41	37.2%
Seven drugs	12	10.9%
Eight drugs	5	4.5%

#### Table 6: Total number of drugs prescribed per patient



#### Fig 6: Total number of drugs prescribed per patient

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#### DISTRIBUTION OF FORMULATION OF TOTAL NUMBER OF DRUGS PRESCRIBED

Intravenous were the major formulations used for administration of drugs in this study (36.98%) followed by Tablet injections (28.38%) and Inhalation (21.93%) and Syrup (12.68%). [Table 7, Figure 7]

#### Table 7: Formulation of total number of drugs prescribed

FORMULATIONS	NO. OF DRUGS (n=465)	IN PERCENTAGE
INTRAVENOUS	172	36.98%
TABLET	132	28.38%
SYRUP	59	12.68%
INHALATION	102	21 93%



Fig 7: Pie chart Representation of prescribed drugs formulation

#### **IV. DISCUSSION**

As per data of the present study, COPD was more common among males as compared to females; this finding is in accordance with results of the previous studies conducted by UNNI, Aswathy et al.<sup>24</sup> Demographic profile of patients who came under this study revealed that most of them were of a low socioeconomic status according to the modified Kuppuswamy scale.<sup>42</sup> this may be because according to the GOLD guideline, people of low socioeconomic status tend to have increased incidence of COPD. This study was conducted for a period of 6 months, the study included 110 patients from IP department of Mallige Hospital. All adult inpatients ≥18 years with chronic obstructive pulmonary disease were included in this study. In this study, majority of the patients belonged to the age group of between 41-60 years (46.3%) which was similar to the study conducted by, Sharon sunil, et al.<sup>25</sup> Average number of drugs per person is an important index of prescription audit. The WHO recommends that the average number of drugs per prescription should be less than two. Mean number of drugs per prescription should be kept as low as possible. In this study, results showed tendency of polypharmacy with maximum number of prescriptions were having 6 drugs (37.2%). It could be due to in-patients nature of the study.

Among 206 drugs prescribed for COPD patients 3 drugs were inappropriately prescribed. The category of drugs like Antibiotic, Short acting beta-2 agonist, Anticholinergic agent and inhaled corticosteroids required more dosage adjustment when compared to other category of drugs. After distribution of the patients based on co-morbid conditions it was observed that Hypertension (29.07%) and Diabetes mellitus (19.82%) were the two most common co-morbid conditions found in most of the patients which increase the risk of COPD. This result conducted with the study done by Tyree H. Kiser, et al.<sup>26</sup> which is supporting this study. Intravenous were the major formulations used for administration of medication in COPD patients (36.98%). The main reason is it may be because of fast effect of the formulation of drugs. WHO recommends lesser use of injection as it helpful in reducing the cost of treatment and its disadvantages. One of the most

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important drug-related problems in patients with COPD is medication dosing errors. The proper dosing of medications for patients with COPD can maximize therapeutic efficacy and minimize toxicity. Proper dosing can also have an economic impact on the health system. Studies have shown that an adverse drug event increases the length of hospitalization and consequently increases cost. Dosage adjustment can result in avoidance of costs associated with drug-related toxicity and in cost savings in terms of drug costs. Clinical pharmacist's works directly with medical professionals and patients usually in a medical centre like, hospital. In present scenario PHARM D should be appointed so that, they can assist physicians to adjust drug dosages in patients with chronic kidney disease. The involvement of a pharmacist at the point of prescription of a drug by a physician is the most effective. The time for decision-making is very important. Physicians and pharmacists can work together to have safe drug prescribing that can be complex and requires stepwise approach to ensure effectiveness, minimize further damage and prevent drug nephrotoxicity.

#### V. CONCLUSION

The present study represents the current prescribing trend for anti COPD agents. Despite the use of drugs according to the availability and physician's preference, it was found in the analysis that majority were in accordance with GOLD criteria recommendations. Most of the patients were only taking the medications offered at the hospital, and not buying the drugs from outside pharmacies, which were unavailable in the hospital. By including these drugs in the central purchase committee list of government, the treatment can be more effective and economy. Several guidelines have been developed worldwide for the management of exacerbation of chronic obstructive pulmonary disease, and these serve as reference standards for clinical practitioners. However, many clinicians practice their own prescribing pattern in treating COPD patients according to their clinical experience. Primary care physicians need to be empowered in appropriate and evidence-based management of exacerbation of COPD. A review of these prescribing patterns and guideline-based use of anti-COPD medications can give better insights into the concept of personalized, yet cost-effective pharmacological management of COPD.

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