

# Observational Study on Prescription Pattern used in Treatment of COPD patients in Hospital of Haryana, India

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## Abstract:

**Background:** The outcomes of irrational prescribing have a detrimental effect on people's health and the economics of society as a whole, wastage of money and creating numerous health risks. **Method:** Patient included in the study from OPD clinics based on their severity like severe moderate & Mild. Parameters of Demographic details like age and gender, smoking history co-morbidity, prescribed medication details & selection of drugs. GOLD guidelines 2023 were used to validate Drug selection process. **Result-** Evaluation of prescription pattern of drugs for COPD, done through Prospective observational study conducted from the period of January 22 to December in 2023 at the Department of Pulmonology medicine. From 393 patients 61.32% of patients were in the 60-79 years age group & 57.3% were males. (57.5%) of the study participants were smokers, (28.71%) of the drugs were taken through oral form and Nebulization was the second most popular medication form. (34.34%). bronchodilators, 36.95% and 34.12% were delivered as inhalation and oral forms.

## Introduction:

Chronic respiratory diseases are a significant global and Indian health concern, contributing to a substantial burden of disease (1). 100 million people in India alone suffer from obstructive lung disorders. COPD, is a medical disorder that is defined by a continuous obstruction of airflow in the lungs. A potentially fatal condition, COPD is frequently misdiagnosed and incurable (2). The incidence of COPD has increased to epidemic levels, impacting about 10% of people over the age of 40. Considering its high frequency and chronic nature, Drug utilization studies are essential to the development of policies of national health that aim to ensure the availability of safe and effective medications and simultaneously address the problem of excessive medication use, which can be expensive, because COPD is a chronic condition with a high prevalence that requires frequent medical visits, hospitalizations for acute exacerbations, and long-term therapy (3). Prescription patterns and drug administration are the main subjects of these research, which aim to minimize drug addiction and misuse while promoting the proper use of medications under observation. It is imperative to acknowledge that improper prescribing methods may lead to ineffective therapy, increased aggravation, worse quality of life, and higher costs.

## Keywords:

chronic obstructive pulmonary disease, prescription utilization pattern, GOLD guidelines Bronchodilators, Drug utilization, Prescription pattern

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A major global health concern, especially in developing countries, is the improper and irrational prescription of medications (4). Inappropriate drug delivery has a negative impact on people's health and financial security, wasting resources and creating a public health risk. 5. In order to investigate and elucidate the social role of drugs, drug usage research is a vital resource. In order to make informed healthcare decisions, these studies contribute to the development of a strong socio-medical and health economic framework. Although drug use is complicated, the World Health Organization (WHO) has created, standardized, and assessed a number of indicators (6). Measurement of drug use in outpatient settings, resource allocation optimization, addressing deviations from expected norms, and strategic planning are all facilitated by these indicators. Based on information from the National Heart, Lung, and Blood Institute. Of the 24 million people afflicted with chronic obstructive pulmonary disease (COPD), only 10 million have a formal diagnosis, meaning that 12 million remain undiagnosed, according to the National Heart, Lung, and Blood Institute. COPD requires continuous care, which may include taking medications incorrectly or insufficiently (7). The goals of COPD pharmacotherapy are to improve overall health and physical activity, reduce the frequency and intensity of exacerbations, and relieve symptoms. For COPD, bronchodilators are the main therapy choice. While one or more long-acting bronchodilators, such as long-acting beta 2 agonists (LABA) and long-acting muscarinic antagonists (LAMA), are advised for the long-term care of patients with mild to severe symptoms, short-acting bronchodilators are administered for immediate symptom alleviation. While inhaled corticosteroids (ICS) are frequently prescribed for the treatment of asthma, their effectiveness in managing COPD is still up for dispute. ICS are frequently used in COPD patients to reduce the chance of developing asthma. Patients with chronic obstructive pulmonary disease should think about getting a second bronchodilator. People who have significant airflow obstruction and two or more COPD exacerbations per year may also benefit from using ICS, LABA, or LAMA.(8) However, evidence suggests that prescribing practices may not always follow GOLD criteria and other national guidelines, which can result in a large number of patients receiving unnecessary ICS prescriptions and perhaps experiencing adverse effects. Numerous studies that compared medication consumption trends to the GOLD guidelines found several shortcomings in the medical treatment of COPD. Prescription monitoring and drug usage assessments

can help identify drug-related problems, raise awareness of drug abuse, and provide input to medical professionals. Studies on drug use have the ability to Prescription monitoring and drug usage assessments can help identify drug-related problems, raise awareness of drug abuse, and provide input to medical professionals. Because drug utilization research offers useful insights into current prescribing trends, it can impact and enhance clinical and pharmacological practices. Thus, the purpose of this study was to determine the frequency of drug use and compliance with the GOLD guidelines for the treatment of COPD. The purpose of this study is to promote the responsible use of available resources and to improve the appropriate use of prescription drugs. The main goal of this study is to provide insight into the prescription practices that are most commonly used by COPD patients who visit the hospital for therapy.

#### **METHODOLOGY**

A one-year observation based prospective study was performed on 393 consecutive cases of COPD at Out Patient Department of pulmonology medicine from January 22 to December 2023. The study included patient demographics, co-morbidities, and prescribing patterns. All patients gave their agreement, and the study was approved by the Institutional Ethics Committee with the reference number SGTU/Ethical Committee

Patients meeting the criteria for severe moderate & mild COPD and attending the outpatient Department of pulmonary Medicine of both genders, aged 18 years and above, with or without co-existing conditions, were included in the study.

Patients declining to provide consent, those under 18 years of age, terminally ill cancer patients, individuals in the intensive care unit (ICU), and pregnant and lactating women were excluded from the study.

Data collection encompassed patient demographics such as age, gender, occupation, smoking history, details of co-existing conditions, and prescribed medications including the route of administration.

A specially designed data entry form was used for data collection. Sociodemographics, smoking history, and prescribed COPD treatment were collected for each patient. Microsoft Excel was used for data analysis and results were presented as percentages..

#### **RESULTS**

In the study of data of prescription of 393 patients [225 males (57.3%) and 168 females (42.7%)], with a mean age of 64.72±10.14 years analyzed Distribution of COPD Patients on the basis of Gender

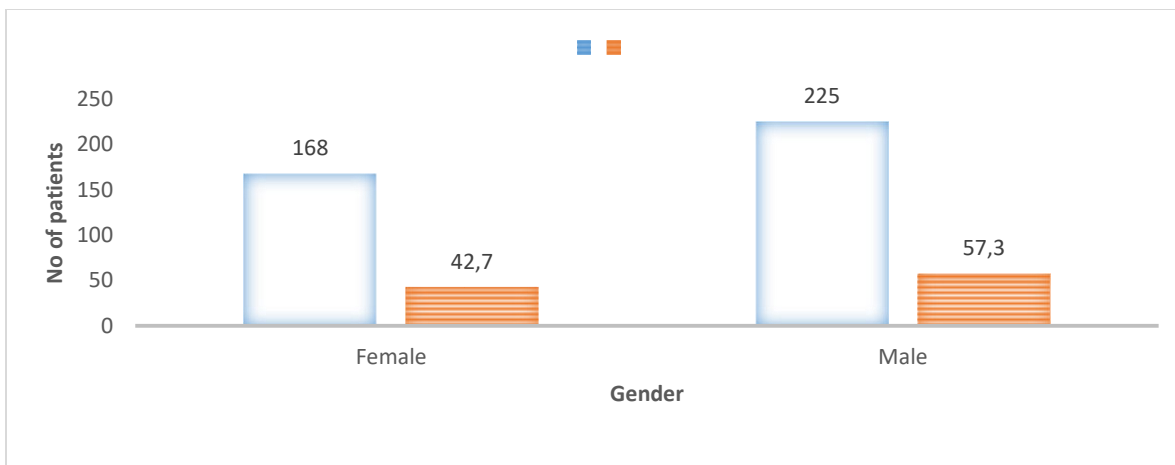


Figure No 1 Distribution of COPD Patients on the basis of Gender

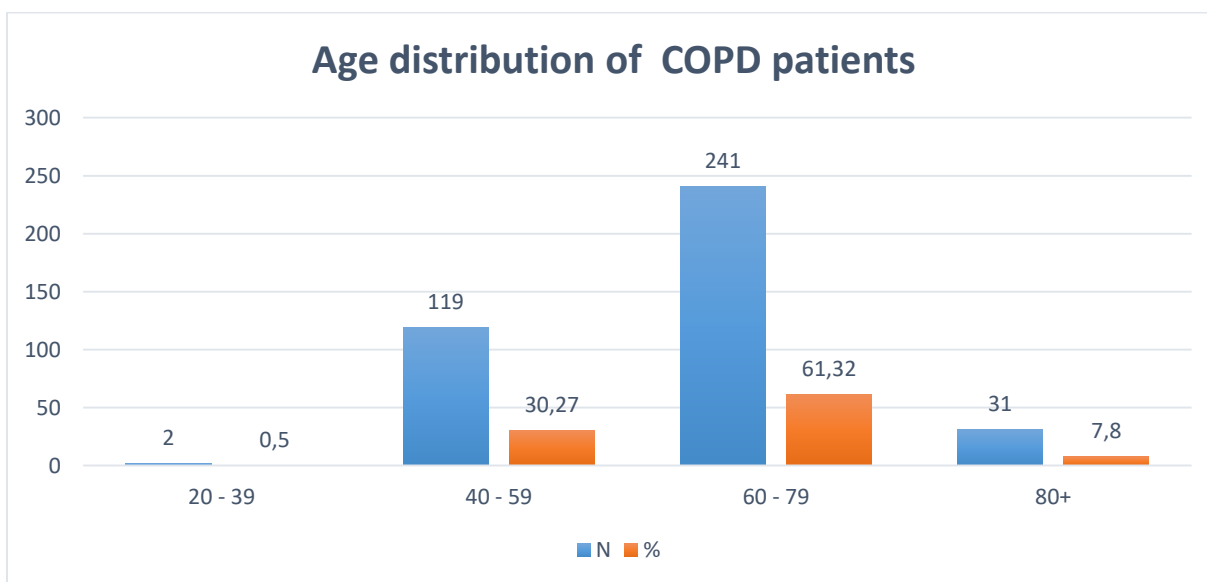


Figure No 2 Distribution of COPD Patients on the basis of Age

Descriptive statistics data regarding distribution of age among participants Out of 393 participants, the majority (241) (61.32%) were between the ages of 60 and 79, followed by 119 (30.27%) between the ages of 40 and 59, 31 (7.8%) between the ages of 80 and above, and 2 (0.5%) between the ages of 20 and 39, as shown in Figure 2. The mean age of the participants was 61.32 years. Smoking status: 393 patients were split according to their addictive tendencies, such as smoking and alcohol intake. Thus, 226 (57.5%) patients were smokers, 128 (32.6%) were nonsmokers, and 39 (9.9%) were quitters.

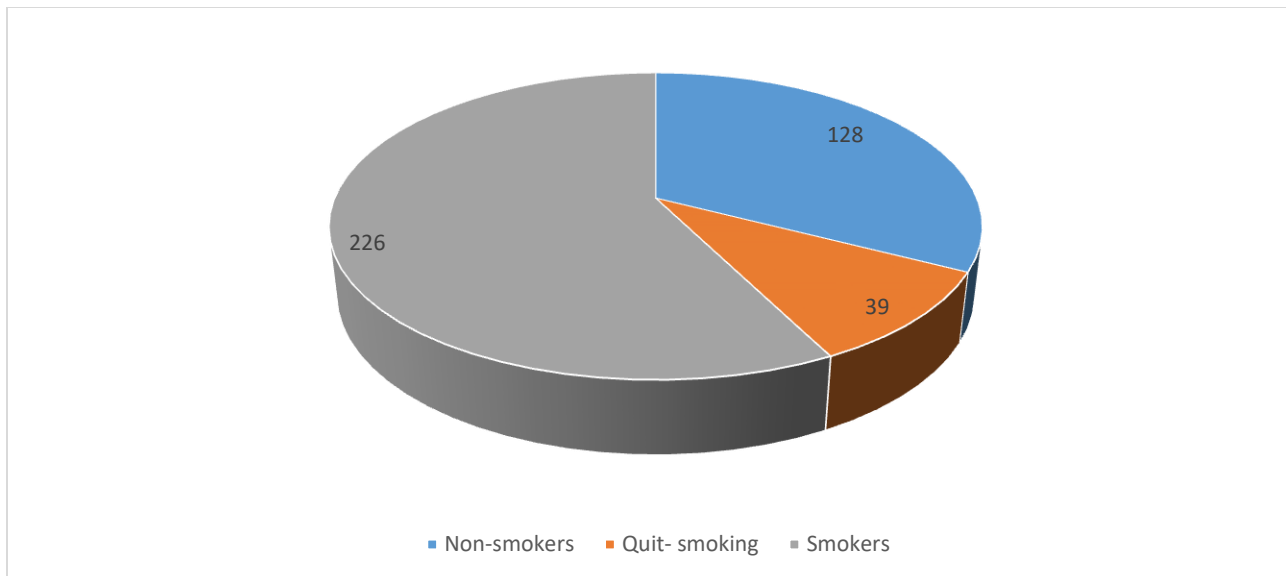


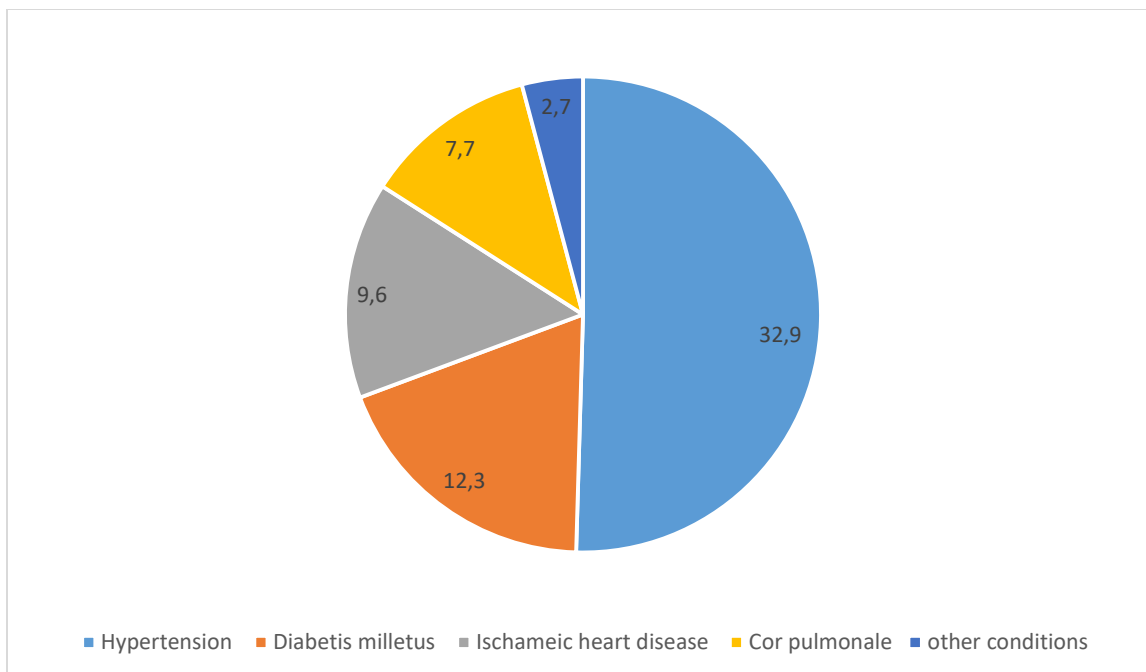
Figure No -3 Smoking status

Table1:Core Indicators of use of drug

Core Indicators of Drug use	Average/percentage
Average number of medications per prescription	5
% of medications administered with generic names	30
% of contacts resulted in antibiotic prescriptions	60.22
% of encounters resulted in injectable prescriptions	51.6
% of pharmaceuticals prescribed were from the necessary drugs list for formulary.	90.23

Table1: Core Indicators of usage of drug

Subject distribution according to comorbidities: Of the 393 participants in this study, 24 (32.9%) had hypertension as a common comorbid condition. These individuals were followed by 9 (12.3%) with other conditions such as diabetes mellitus, 7 (9.6%) with ischemic heart disease (CAD), 3 (7.7%) with pulmonary tuberculosis (PTB), 3 (4.1%) with cor pulmonale, and 2 (2.7%) with other conditions, as shown in the figure.



Anti-hypertensives were administered to 24 (17.76%) subjects, diuretics to 8 (4.38%), nitrates to 16 (11.68%), anti-arrhythmics and alpha-blockers to 4 (2.92%), and hypolipidemics to 2 (1.46%) patients, taking into account the medications for the management of co-existing illnesses. PPIs were provided to 82 patients (59.86%), anti-emetics to 4 patients (2.92%), histamine-2 blockers to 2 patients (1.46%), and probiotics to 2 patients (1.46%) in relation to medications operating on the GIT. The results are shown in Table 2. Additional medications included NSAIDs to 28 (25%), opiate analgesics to 2 (1.78%), multivitamins to 80 (58.4%), and antidepressants to 36 (26.28%).

Class of drugs	N	%
ANTIHYPERTENSIVES	24	17.76
NSAIDS	28	20.44
ANTIDEPRESSANTS	36	26.28
diuretics	8	4.38
nitrates	16	11.68
anti-arrhythmics & alpha-blockers	4	2.92
hypolipidemics	2	1.46
PPI'S	82	59.86
anti-emetics	4	2.92
histamine-2 blockers and probiotics	2	1.46
opiate analgesics	2	1.46
MUTIVITAMINS	80	58.4

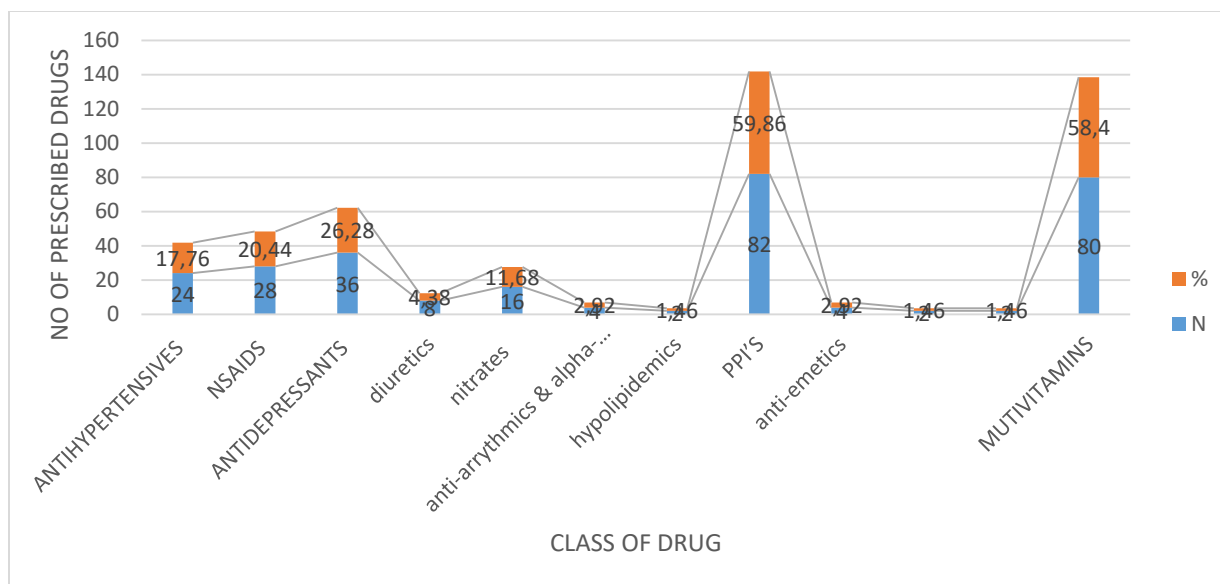


Figure no 4 Distribution of drugs for the management of co-existing conditions

**Drug utilization of antibiotics in COPD patients.**

Type of antibiotic	Number of Prescribed	%
Amoxicillin Clavulanic Acid Ceftriaxone	179	45.5
Azithromycin & levofloxacin	55	13.99
Cefpodoxime	11	2.79
Amikacin	8	2.03
Cefixime	6	1.52
metronidazole	5	1.27
clindamycin, gentamicin and doxycycline	4	1.07

The combination of ceftriaxone amoxicillin, & clavulanic acid was the most often prescribed antibiotic, with 179 (45.5%) cases. Azithromycin and levofloxacin 55 (13.99%), cefpodoxime 11 (2.79%), Amikacin 8 (2.03%), cefixime 6 (1.52%), metronidazole 5 (1.27%), clindamycin, gentamicin, and doxycycline were prescribed to 4 (1.07%) patients (Table 3).

Route of Administration -In this study, the most popular method of drug administration was inhalation (36.95%), which was followed by parenteral (34.34%) and oral (28.71%) routes (figure No5).

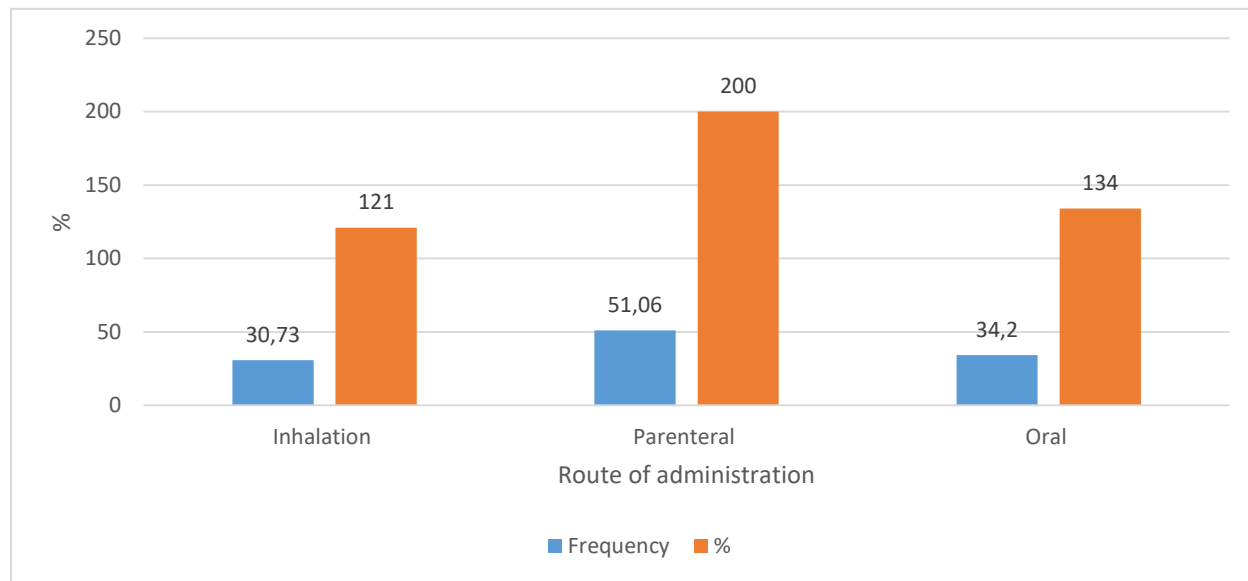


Figure No 5 Route of administration of drugs in COPD patients.

**Prescribing pattern of COPD drugs-**

Table 4: Drug utilization pattern (N=393)

Pattern	Pattern Drugs utilized	Number of times prescribed	Percentage
	Anticholinergic	31	7.7
	Methylxanthines	59	15.4
	Steroids	208	53.8
	Antibiotics	275	71.8
	Leukotriene antagonist	110	28.2
	SABA	245	62.3
	LABA	215	54.7
Number of drugs per prescription	<5	122	31.04
	>5	271	68.9

Drug classes used in the therapy were evaluated, most commonly used drugs were antibiotics (275/71.8%), corticosteroids (208/53.8%), both inhaled and systemic (208/53.8%), leukotriene receptor antagonists (only used in 110 (28.2 %), methylxanthines (59/15.4 %), anticholinergic drugs (31/7.7%), Distribution of drugs in 393 patients, of whom the majority received prescriptions for the bronchodilator combination drug salbutamol (SABA) and ipratropium bromide (SAMA) in 282 (71.8%) of the cases, followed by antibiotics in 275 (69.9%) of the cases for COPD therapy. Subsequently, 208 (53.8%) patients used Budesonide (Corticosteroids), 110 (28.2%) patients used Hydrocortisone, 102 (25.6%) patients used a combination of Mucolytic, Terbutaline (beta agonist), and Exceptrant, 59 (15.4%) patients used Methyl xanthine, 31 (7.7%) participants used Tiotropium bromide (Anticholinergic), and 10 (2.6%) patients used Salbutamol (Bronchodilators) on its own. whose illustration is displayed in Table No. 5

CLASS OF DRUGS	DRUGS	N
SABA	Salbutamol	141
	Terbutaline	43
LABA	formoterol	289
Corticosteroids	Budesonide	208
	Budecort 0.5mg Respules (2ml Each)	
	Budesonide (1mg)	85
	Fluticasone	110
	beclomethasone Methylprednisolone (4mg)	59
	Hydrocortisone	31
Methylxanthines	Theophylline	
Anticholinergic	Tiotropium(9mcg) Glycopyrrolate (25mcg)	
Antihistamincs	Chlorpheniramine Maleate (4mg/5ml) Dextromethorphan Hydrobromide (10mg/5ml)	275
Antibiotics	Cefpodoxime Proxetil (200mg) + Clavulanic Acid (125mg) Cefixime (200mg)	201
Leutriene antagonist	Montelukast (10mg) + Fexofenadine (120mg)	70
	Levocetirizine(5mg)	171
	Ebastine (10mg) + Montelukast (10mg)	35
		64



others	Domperidone (30mg) + Rabeprazole (20mg) Domperidone (10mg) + Omeprazole (20mg) Prucalopride (1mg) S-Amlodipine (2.5mg) Alprazolam (0.25mg) Aceclofenac (100mg) + Paracetamol (325mg) Etoricoxib (60mg) Gabapentin (100mg) + Methylcobalamin (500mcg) Naproxen (10% w/w) Phytorefiel	36
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Distribution of study participants drugs on the basis of monotherapy and combination therapy

It was observed that combination drugs was prescribed 68.9 % times in comparison to the monotherapy 31.1% as represented in Table No 6

COMBINATION OF DRUGS	N
Glycopyrrolate (25mcg) + Formoterol (12mcg) +Buesonide (400mcg)	282
Fluticasone Propionate + Azelastine+Theophylline	110
Terbutaine +guaiphenesin +bromohexiene	102
Salmeterol (50mcg) + Fluticasone Propionate (250mcg)	58
Etophylline +theophylline	72
Levosalbutamol (1.25mg) + Ipratropium bromide (500mcg)	114
Levosalbutamol (1.25mg) + beclomethasone	66
Levocetrine +monetulkast	78

Table No -4 COMBINATION OF DRUGS

#### DISCUSSION

The previous study findings were further validated by this study, showing that males were the predominant group affected by the disease. The age distribution also supported previous evidence, indicating that individuals above 40 years old were the ones primarily admitted during the study period.

In case of gender distribution, the majority of patients were male, accounting for 57.3%, while females made up 42.7%. Our research revealed a higher incidence of COPD in males compared to females, consistent with previous reports by Niffy A. et al (13) and Gigi A. et al. (14). The demographic profile of the patients in this study indicated that

most were smokers. Another possible explanation is that individuals with high tend to have a higher incidence of COPD according to the GOLD guideline. Additionally, a large proportion of patients in this study had co-morbid conditions (n = 302; 77.5%). It may be due to the fact that most of the men smoke and it seems to be an important contributing factor of COPD. People of age group 61-70 years were found to be more affected. The age distribution supported the evidence of the previous studies that only those above 40 years of age were admitted during the period of the study. Regarding the sex wise distribution, majority of the patients were males who accounted for 76.36%. The females accounted for around 23.63%. This only confirmed the finding of the previous study conducted that males accounted for the majority of the disease burden.<sup>13</sup>

In this investigation, Majority of the patients were undergoing combination therapy. All patients were being treated with either oral or inhalational  $\beta$  agonists. Salbutamol was the most commonly used inhalational  $\beta$  agonist at 62.3%, followed by formoterol. Parenteral steroids were administered to 53.8 % of patients, all of whom received hydrocortisone. Steroid inhalers were used by 25% of patients, all of whom were given budesonide. Anticholinergic were prescribed to 7.7% of patients, Antibiotics were utilized by 71.9% of patients in this study, which differed from previous studies showing 52% and 99% usage rates. This variance may indicate varying infection rates among patients with acute exacerbation of COPD in different regions. According to the GOLD criteria, initial management of acute COPD exacerbation involves  $\beta$  agonists, followed by anticholinergic if there is no response. The use of methylxanthines remains controversial due to potential adverse effects. This study found high usage of methylxanthines and lower usage of anticholinergic, possibly due to the easy availability of methylxanthines and limited availability of anticholinergic in the hospital setting. Despite antibiotic use being based on availability and physician preference, the majority of cases aligned with GOLD criteria recommendations.

The demographic characteristics of the patients included in this study indicated that the majority were smokers. The findings of our study were consistent with those reported by Niffy A. et al. (13), highlighting the impact of smoking on various organ systems, leading to the development of several chronic respiratory conditions, particularly chronic obstructive pulmonary disease (COPD). Additionally, elevated levels of carbohydrate deficient transferrin (CDT), increased T lymphocytes and macrophages, as well as an imbalance between oxidants and antioxidants were observed (17).

In terms of drug therapy, all 393 prescriptions analyzed in our study involved the administration of more than three medications, aligning with previous

research conducted by Unni A. et al. (20) and Niffy A. et al. (13). The prescription of multiple drugs for individual patients may indicate the presence of acute and chronic exacerbations of COPD and bronchial asthma, with or without comorbidities, necessitating antibiotic and corticosteroid treatments.

Regarding the medications prescribed, antibiotics were universally administered to all patients, with anticholinergics, short-acting  $\beta_2$  agonists, inhaled steroids, and methylxanthine group drugs being among the most commonly prescribed. Our study findings were consistent with those reported by Vikneswari et al. (23).

In a study conducted by Sharon Sunil et al. (24), 45% of patients received combination therapy, with salbutamol + ipratropium bromide + budesonide being the preferred combination (40%), followed by etophylline + theophylline (22%) and budesonide + formoterol (14%).

Faheemuddin M. D. et al. (25) reported that COPD patients were treated with a combination of bronchodilators, specifically a  $\beta_2$  agonist and an anticholinergic (salbutamol + ipratropium bromide).

In our study, commonly used drug combinations included levocetirizine + montelukast (77%), salbutamol sulphate + ipratropium bromide + budesonide (71.8%), and salmeterol (LABA) + fluticasone (27.9%). These combinations were aimed at reducing COPD symptoms and improving patient outcomes.

The use of drug combinations has been proven effective in reducing COPD symptoms, enhancing the effectiveness of drugs, and decreasing medication dosage. Mir S. Adil et al. (26) found that the combination therapy of LABA/SABA-ICS was significantly superior to LABA/SABA monotherapy in controlling COPD. This combination not only reduced the risk of exacerbations but also improved the quality of life and airflow measures. Additionally, combination therapy with anti-inflammatory properties may help reduce the risks of re-hospitalization or death.

According to Basavaraju Thejur Jayadeva et al. (27), short-acting  $\beta_2$  agonists like salbutamol are commonly prescribed due to their rapid onset and affordability. In our study, injection hydrocortisone (15.01%) was also used to manage acute asthma attacks, preventing the respiratory tract irritation caused by inhaled medication.

In a study conducted by Niffy Abraham et al. (13), the majority of patients received fixed dose combination therapy, including salbutamol sulphate + ipratropium bromide (23.19%) and salbutamol

sulphate + ipratropium bromide + budesonide (42.23%). Another study (28) also showed that most patients were given the same combination therapy, consisting of salbutamol sulphate + ipratropium bromide (23.19%) and salbutamol sulphate + ipratropium bromide + budesonide (42.23%).

However, it is crucial to increase awareness and understanding of COPD, particularly in primary care settings where the majority of undiagnosed COPD patients are initially seen and treated. Healthcare providers must be dedicated to disseminating and implementing evidence-based guidelines in their everyday clinical practices to reverse the current trends of increased morbidity and mortality associated with COPD.

#### CONCLUSION:

Investigation conducted on individuals with COPD, it was observed that there was a higher number of male patients compared to female patients. The majority of the prescribed medications were in line with the guidelines set by the global initiative for chronic obstructive lung disease (GOLD). The primary risk factor identified in this study for the disease was smoking, therefore it is advisable for patients to receive counseling on smoking cessation and the use of masks to prevent inhalation of harmful particles. Additionally, it was noted that none of the patients in this study had received vaccination, hence it is crucial to make vaccinations available to them as recommended by the global initiative for chronic obstructive lung disease. Influenza vaccination should be considered for all COPD patients, while Pneumococcal vaccination is recommended for patients aged 65 and above.

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  28. CI, confidence interval; COPD, chronic obstructive pulmonary disease; HR, hazard ration; LABA+ICS, long-acting  $\beta_2$ -agonists and inhaled corticosteroids; LABA, long-acting  $\beta_2$ -agonists, LAMA, long-acting muscarinic antagonists; SABA, short-acting  $\beta_2$ -agonists; SAMA, short-acting muscarinic antagonists.