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A STUDY ON THE CURRENT TRENDS IN PRESCRIBING PATTERN OF DRUGS USED IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASEATA TERTIARY CARE TEACHING HOSPITAL

Syed Areefulla Hussainy[1]*, Yasmeen Sultana[2], Asma Ali Shareef[3], Syeda Fadiya Kulsum[4], Bibi Farhana[5]

[1]MESCO College of Pharmacy, Mustaidpura, Karwan Road, Hyderabad.

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Abstract:

Aim & objective: *The principle aim of our study was to evaluate the current trends in prescribing pattern of drugs used in the treatment of chronic obstructive pulmonary disease and to check the rationality of the prescription at a tertiary care teaching hospital.*

Methodology: *A Prospective and observational study was carried out at the Department of general medicine in Osmania General Hospital, a tertiary care teaching hospital for a period of 6 months. All the patients of either sex and with co-morbidities attending General medicine department with established chronic obstructive pulmonary disease were included in the study. In-patients already diagnosed of chronic obstructive pulmonary disease and are on treatment. In this Study, patients of more than 18 years of age group were included. Patients diagnosed under 18 years of age, pregnant and lactating women, refusal to be a part of the study and Out-Patients were excluded.*

Results: *During the study period, a total 100 Patients were enrolled. Out of which 92% were male and 8% were female. Among the total patients, common age group was 60-69 years. It was found that 75% of subjects were addicted to smoking and 48% of patients were admitted with stage-4 COPD, it was also noticed that 33% patients were admitted with RTI with corpulmonale as a comorbidity, 85% patients were given oxygen therapy,58% patients were prescribed methylxanthines, 51% were prescribed systemic corticosteroids,41% were prescribed antibiotics,18% were prescribed inhaled corticosteroids,16% were prescribed short acting beta 2 agonist and mucolytics and 10% were prescribed with anticholinergics.*

Conclusion: *In our study, we observed that the incidence of COPD was more common in males.The study population was treated with combination drugs and multidrug therapy out of which inhalation route was the most preferred one.Severity of COPD was calculated based on mMRC scale,risk factors and symptoms.Various classes of drugs prescribed were Methylxanthines, systemic corticosteroids, antibiotics, inhaled corticosteroids, SABA(Short acting beta 2 agonist),mucolytics and anticholinergics.Antibiotics were prescribed irrespective of culture sensitivity test and mostly based on symptoms. Spirometry which is a standard test for the diagnosis of COPD was not performed in this study, so it should be performed according to GOLD guidelines. In our study, vaccinations were not given to the patients so it should be promoted according to GOLD guidelines.*

Keywords: *Chronic Obstructive Pulmonary Disease, Beta 2 Agonist, Anticholinergics, Methylxanthines, Corticosteroids and Antibiotics.*

Corresponding author:

Syed Areefulla Hussainy,

MESCO College of Pharmacy, Mustaidpura, Karwan Road, Hyderabad.

Email: areefulla581@gmail.com

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INTRODUCTION:

In 2001, the National Institutes of Health (NIH) and the World Health Organization (WHO) collaborated to develop the Global Initiative for Obstructive Lung Disease (GOLD) guidelines.These guidelines address a wide variety of topics related to chronic obstructive pulmonary disease (COPD), including current concepts of pathophysiology, and make recommendations regarding diagnosis and treatment. The guidelines are updated yearly, represent an international effort, and are based on the strength of the evidence supporting them.[1] The most recent definition of COPD according to GOLD is as follows:

Chronic Obstructive Pulmonary Disease:

"Chronic obstructive pulmonary disease (COPD) is characterized by chronic airflow limitation and a range of pathological changes in the lung, some significant extra-pulmonary effects, and important comorbidities which may contribute to the severity of the disease in individual patients. Thus, COPD should be regarded as a pulmonary disease, but these significant comorbidities must be taken into account in a comprehensive diagnostic assessment of severity and in determining appropriate treatment."[2]

COPD generally refers to emphysema or chronic bronchitis.Emphysema is pathologically defined and characterized by alveolar wall destruction and airspace enlargement. Chronic bronchitis is clinically defined as a chronic cough for at least 3 months for 2 consecutive years. Its pathologic hallmark involves inflammation and fibrosis of the small airways.Clearly, much overlap exists between these two conditions because both are primarily caused by cigarette smoking. It should also be pointed out that small airway inflammation is an important characteristic of COPD, which appears to correlate with the more severe stages of the disease whether or not the patient has "chronic bronchitis.[1]

Epidemiology:

Chronic obstructive pulmonary disease is an extremely important cause of morbidity and mortality and in 2005 accounted for 1 in every 20 deaths in the United States.For example, the prevalence of COPD more than doubled between 1990 and 2002, making it the fourth leading cause of death in the United States.

A major cause of disability, COPD currently is considered the 11th leading cause of disability worldwide. Current projections suggest that by the year 2020, COPD will be the 5th leading cause of disability worldwide, behind only ischemic heart disease, major depression, traffic accidents, and cerebrovascular disease.[1]

Factors that influence disease development and progression:

- **Genetic factors:** The genetic risk factor that is best documented is a severe hereditary deficiency of alpha- 1antitrypsin (AATD),a major circulating inhibitor of serine proteases. Although AATD deficiency is relevant to only a small part of the world's population, it illustrates the interaction between genes and environmental exposures that predispose an individual to COPD.

- **Age and sex:** Age is often listed as a risk factor for COPD. It is unclear if healthy aging as such leads to COPD or if age reflects the sum of cumulative exposures throughout life. Aging of the airways and parenchyma mimic some of the structural changes associated with COPD. In the past, most studies have reported that COPD prevalence and mortality are greater among men than women, but more recent data from developed countries has reported that the prevalence of COPD is now almost equal in men and women, probably reflecting the changing patterns of tobacco smoking.
- **Lung growth and development:** Processes occurring during gestation, birth, and exposures during childhood and adolescence affect lung growth. Reduced maximal attained lung function (as measured by spirometry) may identify individuals who are at increased risk for the development of COPD. Any factor that affects lung growth during gestation and childhood has the potential for increasing an individual's risk of developing COPD.

- **Exposure to particles:** Cigarette smokers have a higher prevalence of respiratory symptoms and lung function abnormalities, a greater annual rate of decline in FEV1, and a greater COPD mortality rate than non-smokers .Other types of tobacco (e.g., pipe, cigar, water pipe)and marijuana are also risk factors for COPD. Passive exposure to cigarette smoke, also known as environmental tobacco smoke (ETS), may also contribute to respiratory symptoms and COPD by increasing the lung's total burden of inhaled particles and gases.

- **Socioeconomic status:** Lower socioeconomic status is associated with an increased risk for developing COPD but the components of poverty that contribute are unclear.It is not clear, however, whether this pattern reflects exposures to indoor

and outdoor air pollutants, crowding, poor nutrition, infections, or other factors related to low socioeconomic status.[2]

Signs and Symptoms:
The diagnosis of COPD is made based on the patient's symptoms, including cough, sputum production, and dyspnea, and a history of exposure to risk factors such as tobacco smoke and occupational exposures. Patients may have these symptoms for several years before dyspnea develops and often will not seek medical attention until dyspnea is significant. a diagnosis of copd should be considered in any patient who presents with chronic cough, sputum production, or dyspnea and who has risk factors for the disease.[3]

Pathogenesis:
The inflammation observed in the respiratory tract of COPD patients appears to be a modification of the normal inflammatory response of the respiratory tract to chronic irritants such as cigarette smoke.Although some patients develop COPD without smoking, the nature of the inflammatory response in these patients is as yet unknown. Oxidative stress and an excess of proteinases in the lung are likely to further modify lung inflammation. Together, these mechanisms may lead to the characteristic pathological changes in COPD.

Inflammatory cells:
COPD is characterized by increased numbers of macrophages in peripheral airways, lung parenchyma and pulmonary vessels, together with increased activated neutrophils and increased lymphocytes that include Tc1, Th1, Th17 and ILC3 cells. In some patients, there may also be increase in eosinophil count, Th2 or ILC2 cells, especially where there is clinical overlap with asthma. All of these inflammatory cells, together with epithelial cells and other structural cells release multiple inflammatory mediators. A recent study suggests that local IgA deficiency is associated with bacterial translocation, small airway inflammation and airway remodeling.

Inflammatory mediators:
The wide variety of inflammatory mediators that have been shown to be increased in COPD patients attract inflammatory cells from the circulation (chemotactic factors), amplify the inflammatory process (pro-inflammatory cytokines), and induce structural changes (growth factors). *Peribronchiolar and interstitial fibrosis.* Peribronchiolar fibrosis and interstitial opacities have been reported in patients with COPD or those who are asymptomatic smokers. An excessive production of growth factors may be found in smokers or those with preceding airway inflammation who have COPD. Inflammation may precede the development of fibrosis or repeated injury of the airway wall itself may lead to excessive production of muscle and fibrous tissue. This may be a contributing factor to the development of small airways limitation and eventually the obliteration that may precede the development of emphysema.

Pathophysiology:
There is now a good understanding of how the underlying disease process in COPD leads to the characteristic physiological abnormalities and symptoms. For example, inflammation and narrowing of peripheral airways leads to decreased FEV1. Parenchymal destruction due to emphysema also contributes to airflow limitation and leads to decreased gas transfer. There is also emerging evidence to suggest that in addition to airway narrowing, there is a loss of small airways, which may contribute to airflow limitation. [2]

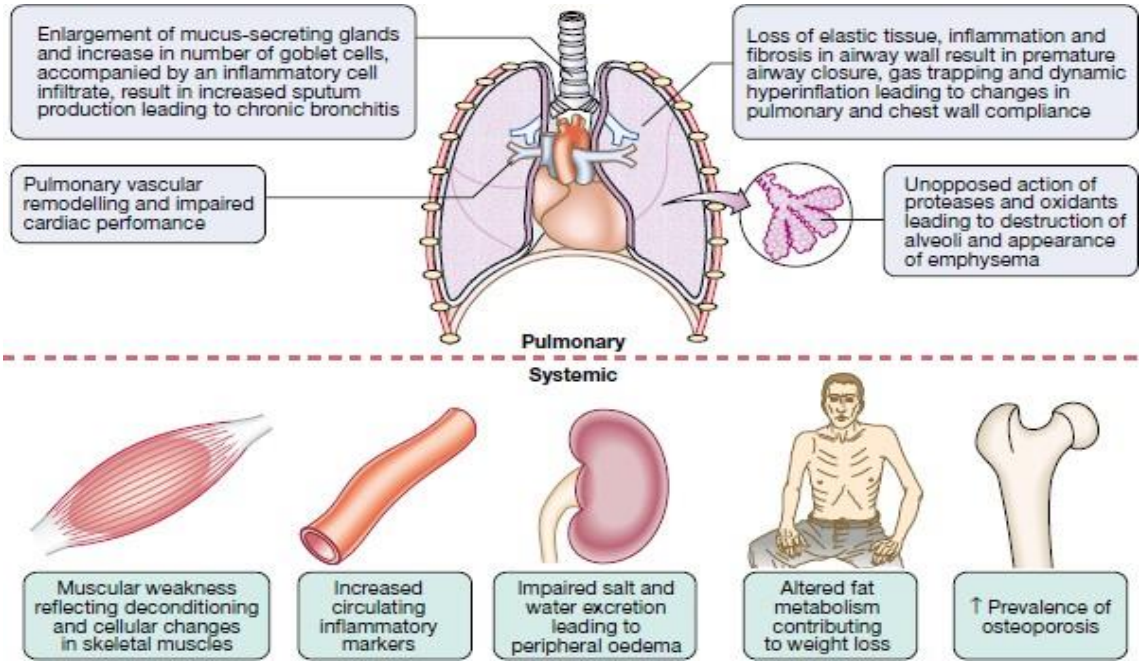

Figure 1:Pathophysiology of COPD

DIAGNOSIS:

COPD should be considered in any patient who has dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease. Spirometry is required to make the diagnosis in this clinical context; the presence of a post-bronchodilator FEV1/FVC < 0.70 confirms the presence of persistent airflow limitation and thus of COPD in patients with appropriate symptoms and significant exposures to noxious stimuli.

The hallmark of COPD is airflow obstruction Pulmonary function testing shows airflow obstruction with a reduction in FEV1 and FEV1/FVC the GOLD added an additional classification system incorporating symptoms and exacerbation history; the utility of this system remains to be defined. Arterial blood gases and oximetry may demonstrate resting or exertional hypoxemia. Arterial blood gases provide additional information Pco2 and pH. The change in pH with Pco2 is 0.08 units/10 mm Hg acutely and 0.03 units/10 mmHg in the chronic state. Knowledge of the arterial pH therefore allows the classification of ventilatory failure, defined as Pco2 >45 mmHg, into acute or chronic conditions. The arterial blood gas is an important component of the evaluation of patients presenting with symptoms of an exacerbation. An elevated hematocrit suggests the presence of chronic hypoxemia, as does the presence of signs of right ventricular hypertrophy. COPD should be considered in any patient who has dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease. Spirometry is required to make the diagnosis in this clinical context; the presence of a post- bronchodilator FEV1/FVC < 0.70 confirms the presence of persistent airflow limitation and thus of COPD in patients with appropriate symptoms and significant exposures to noxious stimuli.

A simple measure of breathlessness such as the Modified British Medical Research Council(mMRC) Questionnaire was considered adequate for assessment of symptoms, as the mMRC relates well to other measures of health status and predicts future mortality risk.[2]

Classification of severity of airflow limitation:

The classification of airflow limitation severity in COPD is shown in **Table.** Specific spirometric cut-points are used for purposes of simplicity. Spirometry

should be performed after the administration of an adequate dose of at least one short-acting inhaled bronchodilator in order to minimize variability.

Table-2:Classification of airflow limitation severity in COPD

Table 2.4. Classification of airflow limitation severity in COPD (Based on post-bronchodilator FEV_1)		
In patients with $FEV_1/FVC < 0.70$:		
GOLD 1:	Mild	$FEV_1 \geq 80\%$ predicted
GOLD 2:	Moderate	$50\% \leq FEV_1 < 80\%$ predicted
GOLD 3:	Severe	$30\% \leq FEV_1 < 50\%$ predicted
GOLD 4:	Very Severe	$FEV_1 < 30\%$ predicted

AIM AND OBJECTIVES:

- To study the current trends in prescribing pattern of drugs used in the treatment of chronic obstructive pulmonary disease at the department of general medicine of a tertiary care teaching hospital
- To check the rationality of the prescription as per GOLD guidelines.

NEED FOR STUDY:

- COPD is a leading cause of morbidity and mortality worldwide.
- The study of prescribing pattern seeks to monitor, evaluate if necessary, suggest modifications in the prescribing behaviour of medical practitioners to make medical care rational.
- The prescribing pattern varies from country to country, patients to patients and from prescriber to prescriber.
- The purpose of the study was evaluation of the drug prescribing patterns need to be done to enable suitable modifications in prescription of drugs to increase the therapeutic benefit and decrease the adverse effects.
- To evaluate the duration of therapy, dose strength and dosage and to correct over- prescribing and interactions.

METHODOLOGY:

A Prospective and Observational study was carried out in the Department of General Medicine, at Osmania General Hospital.Hyderabad, Telanagana State.for a period of 6 months with a sample size of 100 patients.

MATERIALS AND METHODS:

Suitable Data collection forms were prepared and the data collection was done in the prepared forms.
The Data is Collected using Prepared forms
Follow up of Patients is done to Evaluate
Assessment and Rationality of Prescription
Assessment and Classification of Collected Data
Evaluation and Analysis of Collected Data

DATA ANALYSIS:

Data Analysis is done based on the Parameters assessed and analyzed. The data is represented and the results are made by Graphical Data Representation

PLAN OF WORK:

Suitable Data Collections forms were prepared/ Modified to collect the details on following.

↓

The Data is collected using Prepared forms

↓

Followup of Patients is done to Evaluate

↓

Assessment and Rationality of Prescription

↓

Assessment and Classification of Collected Data

↓

Evaluation and Analysis of Collected Data

RESULTS:

TABLE No.3 DISTRIBUTION OF DATA BASED ON ADDICTION

ADDICTION	SUBJECTS	PERCENTAGE
SMOKERS	75	75.0%
EX-SMOKERS	12	12.0%
NON-SMOKERS	10	10.0%
TOBACCO CHEWER	1	1.0%
EXP TO SMOKE	3	3.0%

TABLE No.4: DISTRIBUTION OF DATA BASED ON STAGES OF COPD

STAGES	SUBJECTS	PRECENTAGE
STAGE-1	00	0%
STAGE-2	30	30.0%
STAGE-3	22	22.0%
STAGE-4	48	48.0%

TABLE No.5 DISTRIBUTION OF DATA BASED ON CO-MORBIDITEIS

CO-MORBIDITIES	SUBJECTS	PERCENTAGE
Acute exacerbations	31	31%
Cor-pulmonale	33	33%
Acute ex-acerbation+ corpulmonale	18	18%
RTI &DISEASES	33	33%
CVDs	25	25%
CNS DISORDERS	9	9%
RENAL DISEASES	14	14%
LIVER DISEASES	3	3%

TABLE No.6 DISTRIBUTION OF DATA BASED ON OXYGEN OTHERAPY

OXYGEN THERAPY	SUBJECTS	PERCENTAGE
WITH OXYGEN THERAPY	85	85.0%
WITH- OUT OXYGEN THERAPY	15	15.0%

TABLE No.7 DISTRIBUTION OF DATA BASED ON ANTIBIOTIC THERAPY

ANTIBIOTICS	SUBJECTS	PERCENTAGE
AMOXICILLIN+ CLAVULANIC ACID	57	57%
AZITHROMYCIN	65	65%
CEFTRIAXONE	63	63.0%
LEVOFLOXACIN	12	12.0%
PIPERACILLIN+TAZOBACTUM	9	9.0%

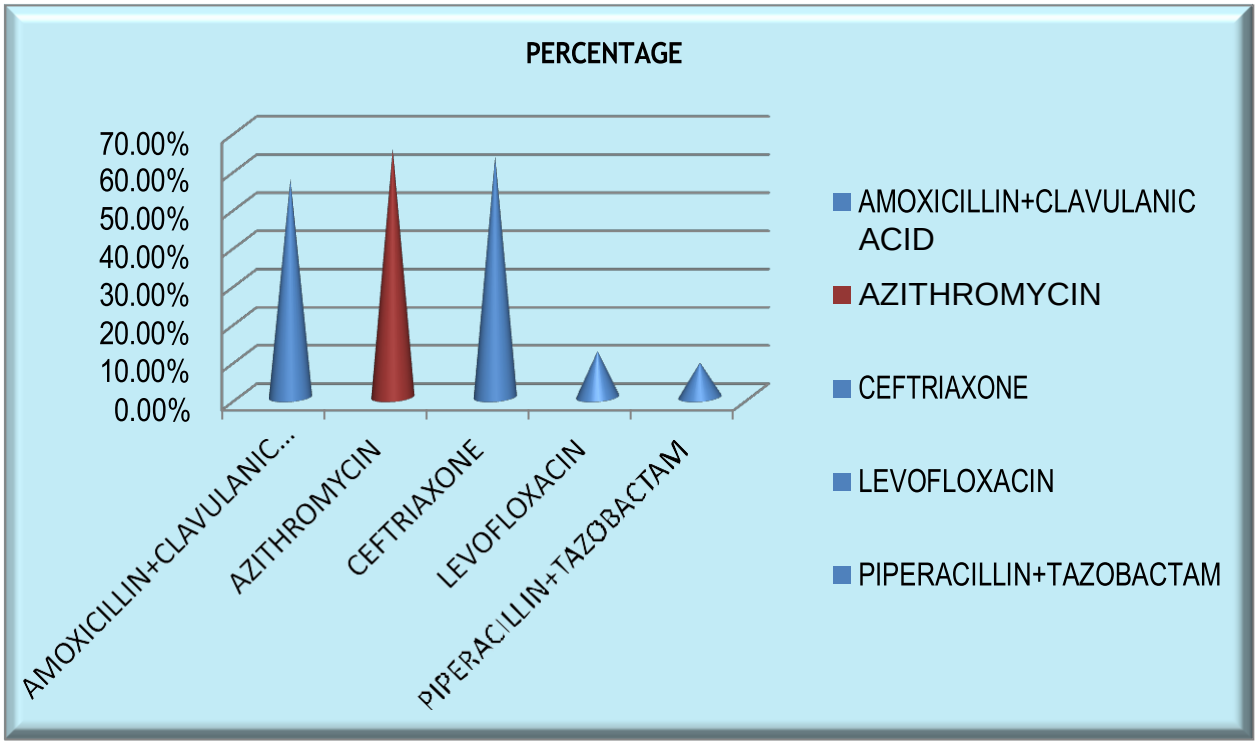

Figure-2 DISTRIBUTION BASED ON ANTIBIOTICS PRESCRIBED.
It was found that majority of the subjects were given Azithromycin antibiotic.

TABLE No.8 DISTRIBUTION OF DATA BASED OF SYRUPS PRESCRIBED

SYRUPS	SUBJECTS	PERCENTAGE
AMBROXOL HYDROCHLORIDE	22	22.0%
AMMONIUM CHLORIDE +CHLORPHENRAMINE+ DEXTROMETHORPHAN +GUAIFENESIN	10	10.0%

TABLE No.9 DISTRIBUTION OF DATA BASED ON CORTICOSTEROIDS PRESCRIBED

CORTICOSTEROIDS	SUBJECTS	PERCENTAGE
HYDROCORTISONE	51	51.0%
PREDNISOLONE	2	2.0%

TABLE No.10 DISTRIBUTION OF DATA BASED ON NEBULIZERS

NEBULISERS	SUBJECTS	PERENTAGE
SALBUTAMOL	23	23.0%
IPTRATROIUM BROMIDE+ SALBUTAMOL	4	4.0%
BUDESONIDE	4	4.0%
SALBUTAMOL+ (IPATROPIUM BROMIDE+SALBUTAMOL)	2	2.0%
SALBUTAMOL+BUDESONIDE	31	31.0%
(IPRATROPIUM BROMIDE+SALBUTAMOL)+ BUDESONIDE	24	24.0%
SALBUTAMOL+IPRATROPIUM BROMIDE+BUDESONIDE	11	11.0%

TABLE No.11 DISTRIBUTION OF DATA BASED ON NEBULIZER THERAPY

PHARMACOTHERAPY	SUBJECTS	PERCENTAGE
NEBULIZER MONOTHERAPY	33	33.0%
DUAL THERAPY	57	57.0%
TRIPLE THERAPY	10	10.0%

TABLE No.12 DISTRIBUTION OF DATA BASED ON PRESCRIBING PATTERN OF DRUGS BASED ON CLASS

CLASS	PERCENTAGE
SYSTEMIC CORTICOSTEROIDS	51%
INHALED CORTICOSTEROIDS	18%
ANTIBIOTICS	41%
ANTICHOLINERGICS	10%
SHORT ACTING BETA-2 AGONIST	16%
MUCOLYTICS	16%
METHYLXANTHINES	58%

TABLE No.13 DISTRIBUTION OF DATA BASED ON THE ROUTE OF ADMINISTRATION (ROA)

ROA	PERCENTAGE
ORAL	65%
PARENTEARAL	39%
INHALATION	100%

TABLE No.14 DISTRIBUTION OF DATA BASED ON PRESCRIBING PATTERN OF DRUGS

DRUGS	PERCENTAGE
SALBUTAMOL	23%
IPRATROPIUM BROMIDE +SALBUTAMOL	4%
BUDESONIDE	4%
THEOPHYLLINE+ETOPHYLLINE	58%
HYDROCORTISONE	51%
PREDNISOLONE	2%
AZITHROMYCIN	65%
AMOXICILIN+CLAVULANIC ACID	57%
CEFTRIAXONE	63%
LEVOFLOXACIN	12%
PIPERACILLIN+TAZOBACTUM	9%

TABLE No.15 RATIONALITY OF THE PRESCRIBTION

RATIONALITY	NO. OF PRESCRIPTIONS	PERCENTAGE
RATIONAL	85	85.0%
IRRATIONAL	15	15.0%

DISCUSSION:

We have performed Prospective observational study on prescriptions of COPD patients. Out of 100 COPD patients,92% were males and 8% were females. The incidence of COPD was high among the age group of 60-69 years(44%) followed by 70-79 years of age(21%).

In the present study, it was found that most of the subjects were addicted to smoking(75%) which is the major risk factor for the development and progression of COPD followed by ex- smokers(12%),exposure to smoke(3%) and tobacco chewers(1%) which is in accordance with other studies conducted by Maqusood

et al.(2017), Niffy et al.(2017),Tamizh mani et al.(2016), Shrestha et al.(2015) stating that most of the subjects with COPD are smokers.

After examining the subjects according to stages of COPD,it was found that majority of the subjects were admitted with stage-4 COPD (30%) followed by stage-2(22%). We assessed that majority of the subjects had various comorbidities like corpulmonale and RTI's(33%) followed by acute exacerbations(31%),cardiovascular diseases(25%),acute exacerbations and corpulmonale(18%),renal diseases(14%),CNS disorders(9%),Liver diseases(3%).

Based on oxygen therapy,it was found that majority of the subjects were admitted with stage-4 COPD and resulted in requirement of oxygen inhalation.Oxygen inhalation at 2- 6lit/min was given depending on ABG(Arterial blood gas) and pulse oximetry($PaSO_2$) values.

After analyzing antibiotic therapy,it was found that majority of the subjects were prescribed azithromycin(65%) followed by ceftriaxone(63%),amoxicillin+clavulanic acid(57%),levofloxacin(12%) and Piperacillin+Tazobactum(9%) which is in compliance with previous studies conducted by Mahmoodan et al.(2017),Niffy et al.(2017),Tamizh mani et al.(2016),Shrestha et al.(2015) and Campos et al.(2015) stating that antibiotics were most commonly used drugs for COPD .

For symptoms like excessive cough with sputum, mucolytic agents and expectorants like Ambroxol Hcl(22%) syrup and Ammonium chloride+Chlorpheniramine maleate + dextromethorphan+guaifenesin(10%) syrup were prescribed. Anti-inflammatory agents prescribed were corticosteroids among which hydrocortisone was mostly used accounting for 51% followed by prednisolone(2%).

In present study, various classes of drugs prescribed. Salbutamol and budesonide combinational nebulizer therapy was given accounting for 31% followed by ipratropium bromide+salbutamol+budesonide(24%).We assessed that dual nebulizer therapy was most commonly used accounting for 57% followed by monotherapy(33%) and triple therapy(10%). In our study, methylxanthines(58%) being the highest prescribed class of drug followed by corticosteroids(51%),antibiotics(41%),inhaled corticosteroid (18%),SABA and mucolytics(16%) and anticholinergics(10%).

Among the various routes of administration of drugs, inhalational route was the most preferred route of administration(100%) followed by oral(65%) and intravenous route(39%).

The prescribing pattern of drugs revealed azithromycin was highly prescribed accounting for 65% followed by ceftriaxone(63%),theophylline+etophylline(58%),Amoxicillin+clavulanic acid(57%),hydrocortisone(51%),salbutamol(23%),levofloxacin(12%),piperacillin+tazobactam(9%),[Ipratropium+salbutamol] + budesonide(4%) and prednisolone(2%).

The present study reveals the prescribing pattern of drugs used in the treatment of mild to very severe COPD stating that most of the subjects were admitted with stage-4 COPD followed by stage-2.Drugs prescribed for the treatment of COPD were according to GOLD guidelines. Methylxanthines were the major class of drugs preferred for the improvement of symptoms as they inhibit phosphodiesterase enzyme leading to bronchodilation. Azithromycin was the most commonly prescribed antibiotic for treating exacerbations. SABA(Short acting beta 2 agonist) and inhaled corticosteroids were used in combination to prevent disease progression.

Out of 100 prescriptions, 85% were rational as they were given in accordance with the GOLD guidelines and 15% were irrational due to initial use of antibiotics and inhaled corticosteroids.

According to the GOLD guidelines, spirometry is the standard diagnostic test for the detection of COPD but it was not performed due to non-availability of device at the study site. LABA(Long acting beta 2 agonist) were not used due to their slow onset of action. In our study, SABA were preferred over LABA due to their rapid onset of action and better therapeutic efficacy. Initial use of antibiotics and systemic corticosteroids were preferred in some of the subjects, although it reduced mortality and morbidity but resulted in antibiotic resistance. According to GOLD guidelines, Influenza and Pneumococcal vaccinations should be given to the subjects to prevent further infections but in our study, subjects were not given any of the vaccinations.

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CONCLUSION:

In the present study, 100 prescriptions of COPD patients were evaluated based on the prescribing pattern of drugs used in the treatment of mild to very severe COPD stating that most of the subjects were admitted with stage-4 COPD followed by stage-2. In our study, we observed that the incidence of COPD was more common in males. The study population was treated with combination drugs and multidrug therapy out of which inhalation route was the most preferred one. Severity of COPD was calculated based on mMRC scale, risk factors and symptoms. Various classes of drugs prescribed were Methylxanthines, systemic corticosteroids, antibiotics, inhaled corticosteroids, SABA(Short acting beta 2 agonist), mucolytics and anticholinergics. Drugs prescribed for the treatment of COPD were according to GOLD guidelines. Methylxanthines were the major class of drugs preferred for the improvement of symptoms Azithromycin was the most commonly prescribed antibiotic for treating exacerbations. SABA(Short acting beta 2 agonist) and inhaled corticosteroids were used in combination to prevent disease progression.Antibiotics were prescribed irrespective of culture sensitivity test and mostly based on symptoms.

Spirometry which is a standard test for the diagnosis of COPD was not performed in this study, so it should be performed according to GOLD guidelines. In our study, we found that vaccinations were not given to the patients so it should be promoted according to GOLD guidelines to prevent infections and exacerbations. It was found that majority of the prescriptions were rational(85%) and were in accordance with the GOLD guidelines.

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