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ASSESSMENT OF PRESCRIPTION PATTERNS OF DRUGS USED IN COPD PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Chronic Obstructive Pulmonary Disease (COPD), a common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. This was a prospective, observational study carried out among patients of COPD in a tertiary care hospital of Dehradun to evaluate prescription pattern monitoring studies (PPMS). Study was carried out by reviewing prescription of 120 COPD patients. Out of 120 patients 67.5% were male and 32.5% were females. The majority of the patients were in age group of 56 - 60 years (34.16%) followed by 51 - 55 years (24.16%), 46 - 50 years (14.16%), 61 - 65 years (9.16%). Among 120 patients, 65.83% were smokers, 34.16% were non-smokers. Etiologic assessment reflected that 68.33% patients belongs to low socioeconomic status followed by exposure to biomass smoker 8.33%. Out of 120 patients, 53.33% were not having any other co-morbid condition and the most common co-morbidity found in remaining patients was hypertension 17.5%. Most commonly prescribed drugs were bronchodilators (22.38%), followed by Antibiotics (18.16%) and corticosteroids (17.62%). Most commonly prescribed bronchodilators drugs were beta-sympathomimetics (52.65%), corticosteroids drugs were Inhaled corticosteroids (61.96%) and antibiotics drugs were beta lactam antibiotics (54.49%). Among all drugs prescribed, 63.02% was prescribed as monotherapy and remaining 36.97% was prescribed as combination therapy. Most commonly prescribed combination drug therapy was salbutamol + budesonide (22.5%). Most commonly prescribed dosage forms were oral dosage forms (77.19%). Due to high value of average number of drugs per patient, problem of concern was polypharmacy which requires the control through rational prescribing practices the drugs prescribing practices in the COPD treatment.

KEYWORDS: COPD, Bronchodilators, Prescribing pattern, Corticosteroids, Polypharmacy.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is not a single disease but an umbrella term used to describe chronic lung disease that causes limitations in lung airflow. The Global Initiative for Chronic Obstructive Lung Disease (GOLD), a project initiated by the national heart, lung, and blood institute (NHLBI) and the world health organization (WHO), defines COPD as Chronic Obstructive Pulmonary Disease, a common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and co-morbidities contribute to the overall severity in individual patients. The more familiar terms 'chronic bronchitis' and 'emphysema' are no longer used, but are now included within the COPD diagnosis. COPD is a chronic, non-communicable disease which poses a continuous burden on health care infrastructure. More than 3 million people died due to COPD in 2012, which is equal to 6% of all deaths causes. Nearly 90% of COPD mortality has been attributed to low and middle-income countries. COPD prevalence is 5% among Indian males and approximately 3.2% among Indian females over 35 years of age. The most common symptoms of COPD are breathlessness, excessive sputum production, and a chronic cough.

COPD is a life-threatening lung disease that interferes with normal breathing. According to the WHO estimates (2004), currently 64 million people have COPD and 3 million people died of COPD. WHO predicts that COPD will become the 3rd leading cause of death worldwide by 2030. Almost 90% of COPD deaths occur in low and middle income countries, where effective strategies for prevention and control are not always implemented or accessible.

COPD is a leading cause of world-wide mortality and disability. On average ~5-15% of adults in industrialized countries have COPD defined by spirometry. In 1990, COPD was considered to be at the 12th position world-wide as a cause of combined mortality and disability but is expected to become the 5th cause by the year 2020.

According to estimates of the WHO, about 80 million patients over the world suffered from COPD in 2005, whereas it accounts for 5% of all deaths. COPD is currently the 4th major cause of death worldwide. The prevalence is estimated to be about 1% worldwide, but is about 2 times higher in western societies, and often under estimated due to misdiagnosis. The burden of COPD for the patient is high as patients experience a poorer quality of life, suffer from co-morbidities (3.7 co-morbidities per patient), and direct healthcare costs range from 0.28 billion euros in the Netherlands (in 2000) to 20.9 billion dollars in the USA (in 2004). Prevalence of 251 million cases of COPD globally in 2016. Globally, it is estimated that 3.17 million deaths were caused by the disease in 2015 (that is, 5% of all deaths globally in that year). More than 90% of COPD deaths occur in low and middle income countries.[1-3]

Tobacco is a legal drug which is currently responsible for the deaths of an estimated 6 million people across the world each year, with many of these deaths occurring prematurely. Tobacco smoking is associated with morbidity and mortality from non-communicable respiratory diseases (NCD's), including about 600000 people who are estimated to die every year from the effects of second-hand smoke. Globally, 84% of smokers live in developing and transitional economy countries. Tobacco smoke potentiates the detrimental effects of biomass smoke exposure.

The WHO stated that in 2015, over 1.1 billion people smoked tobacco, males smoked tobacco more than females, and although it is declining worldwide and in many countries, the prevalence of tobacco smoking appears to be increasing in the eastern Mediterranean and Africa.[4]

The numbers of patients with COPD are increasing rapidly in Uttarakhand. Smoke emitting during smoking and stove burning is a major reason for the increasing number of COPD patients. In this backdrop, on behalf of the Pulmonary Medicine Department of Shri Mahant Indiresh Hospital, experts are brainstorming on the high-tech techniques used in the treatment of symptoms of COPD and the changing face of medical management of COPD is being emphasized. This study was undertaken to assess the prescription pattern of the drugs in COPD patient, because this type of study was not previously done in our hospital or even in the state.

METHODOLOGY

Study design: Prospective observational study

Study Site: The study was conducted in General Medicine and Pulmonary Medicine Out-patient Department of Shri Mahant Indiresh Hospital, Dehradun, Uttarakhand.

Study Duration: The study duration was 6 months.

Study Criteria

- ***Inclusion Criteria***

i. All patients attending OPD of General Medicine and Pulmonary Medicine diagnosed with COPD.
ii. COPD patients with or without co-morbid condition.
iii. Both genders.

- ***Exclusion Criteria***

i. All the in-patients of concerned department.
ii. Patients who does not gave consent to participate in the study.
iii. Patients from pediatrics, pregnancy and lactating groups.

Source of Data

The study data was collected from the following sources:

1. Direct interview of patients at OPD of General Medicine and Pulmonary Medicine Department.
2. Data Collection Form provides the information regarding the demographic details of the patient which includes age, gender, occupation, social history, past medical history and prescription details which includes medicines prescribed, dose, frequency, duration and dosage form.

Data Collection

Study data was collected in the format containing patients demographics as well as medicines related information (Appendix-I) after obtaining informed consent (Appendix-II).

Study Procedure

The study was carried out after getting approval from the Institutional Review Board. Permission to carry out the study was also obtained from Head of General Medicine and Pulmonary Medicine Departments before starting the study. Data from patients attending the respective OPDs diagnosed with COPD during the study period was collected. Detailed information on age, gender, diagnosis, drugs used including name of the drug, dosage schedule (dosage form, route, and frequency) was recorded from the prescriptions given to the patients. The brand names of the drugs

prescribed was decoded to generic names using latest version of standard Current Index of Medical Specialities (CIMS) India - (October 2018 - January 2019). Rationality of prescribing the drugs was evaluated by using the WHO core drug prescribing indicators.

Data Analysis

Data was analyzed by preparing tables and graphs using Microsoft excel.

RESULTS

❖ **Assessment of Prescribing Pattern among COPD Patients**

- **Categorization of drug therapy prescribed**

A sum total of 925 drugs were prescribed among 120 Patients. Table 6 and Figure 6 showed that most commonly prescribed drugs were bronchodilators (22.38%) followed by antibiotics (18.16%), corticosteroids (17.62%), antacids (12%), expectorants (11.56%), mucolytics (6.16%), antihistamines (5.08%), leukotriene antagonist (4.54%), oxygen inhalation (1.18%), opioids (0.75%) and antitussive (0.54%).

Table 6: Categorization of drug therapy among COPD patients.

S. No.	Class of Drugs	Number of Drugs (%) (n = 925)
1.	Bronchodilators	207 (22.38%)
2.	Antibiotics	168 (18.16%)
3.	Corticosteroids	163 (17.62%)
4.	Expectorants	107 (11.56%)
5.	Mucolytics	57 (6.16%)
6.	Antihistamines	47 (5.08%)
7.	Leukotriene antagonist	42 (4.54%)
8.	Antacids	111 (12.00%)
9.	Oxygen inhalation	11 (1.18%)
10.	Opioids	07 (0.75%)
11.	Antitussive	05 (0.54%)

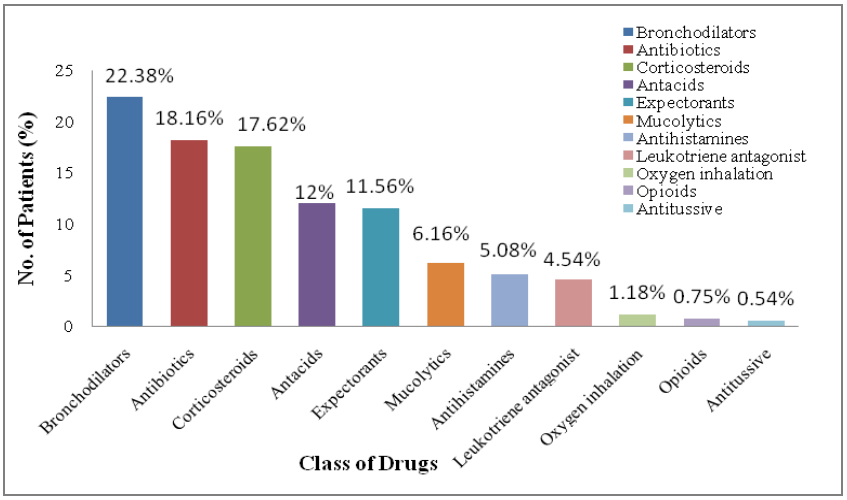

Figure 6: Categorization of drug therapy among COPD patients.

- **Most commonly prescribed drugs**

➢ **Distribution of prescribed bronchodilators**

Table 7 and Figure 7 showed that beta-sympathomimetics (52.65%), methyllxanthines (31.88%) and anticholinergics (15.45%) were mostly prescribed drugs among bronchodilators.

Table 7: Distribution of prescribed bronchodilators.

S. No.	Bronchodilators	No. of Drugs (%) (n = 207)
1.	Beta-sympathomimetics	109 (52.65%)
2.	Methyllxanthines	66 (31.88%)
3.	Anticholinergics	32 (15.45%)

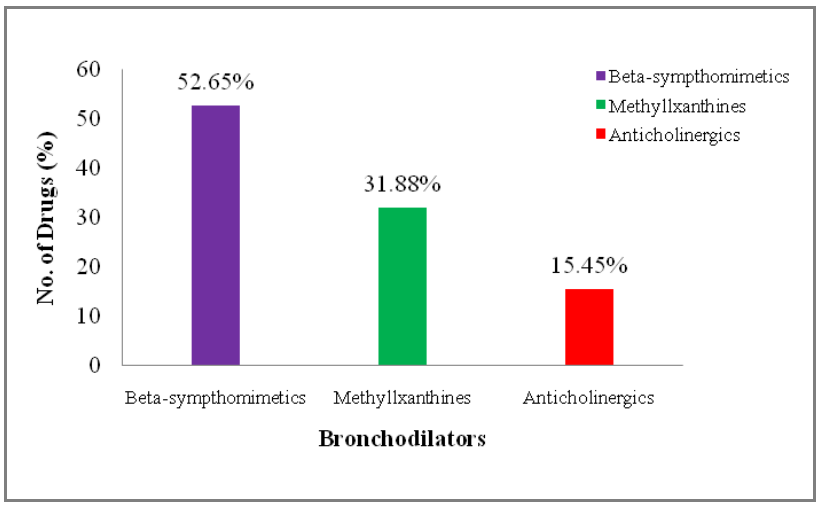

Figure 7: Distribution of prescribed bronchodilators.

➢ **Distribution of prescribed antibiotics**

Table 8 and Figure 8 showed that beta-lactam antibiotics (54.49%), macrolide antibiotics (23.19%), fluoroquinolones (13.69%), aminoglycosides (4.16%), oxazolidinones (2.38%), lincosamide antibiotics (1.19%) and tetracyclines (0.59%) were mostly prescribed drugs among antibiotics.

Table 8: Distribution of prescribed antibiotics.

S. No.	Class of antibiotics	No. of Drugs (%) (n = 168)
1.	Beta lactam antibiotics	91 (54.49%)
2.	Macrolide antibiotics	40 (23.19%)
3.	Fluoroquinolones	23 (13.69%)
4.	aminoglycosides	07 (4.16%)
5.	Oxazolidinones	04 (2.38%)
6.	Lincosamide antibiotics	02 (1.19%)
7.	Tetracyclines	01 (0.59%)

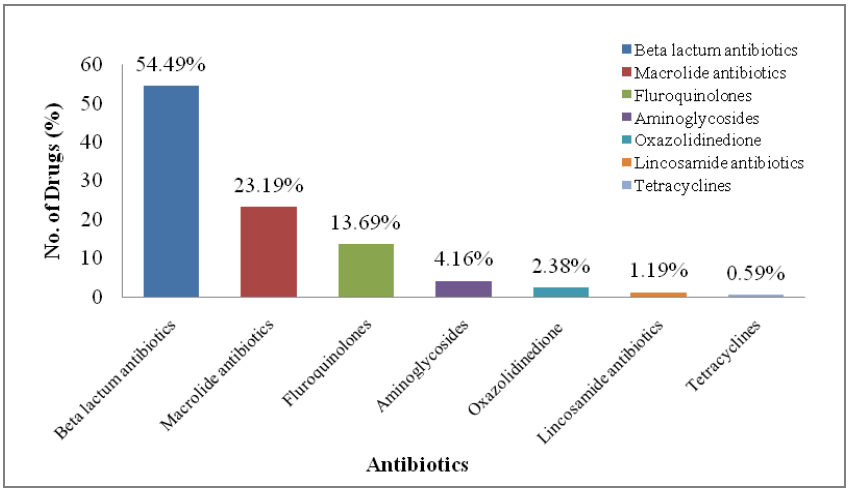

Figure 8: Distribution of prescribed antibiotics.

➢ **Distribution of prescribed corticosteroids**

Table 9 and Figure 9 showed that inhaled corticosteroids (61.96%) and systemic corticosteroids (38.03%) were mostly prescribed drug categories among corticosteroids.

Table 9: Distribution of prescribed corticosteroids.

S. No.	Corticosteroids	No. of Drugs (%) (n = 163)
1.	Inhaled corticosteroids	101 (61.96%)
2.	Systemic corticosteroids	62 (38.03%)

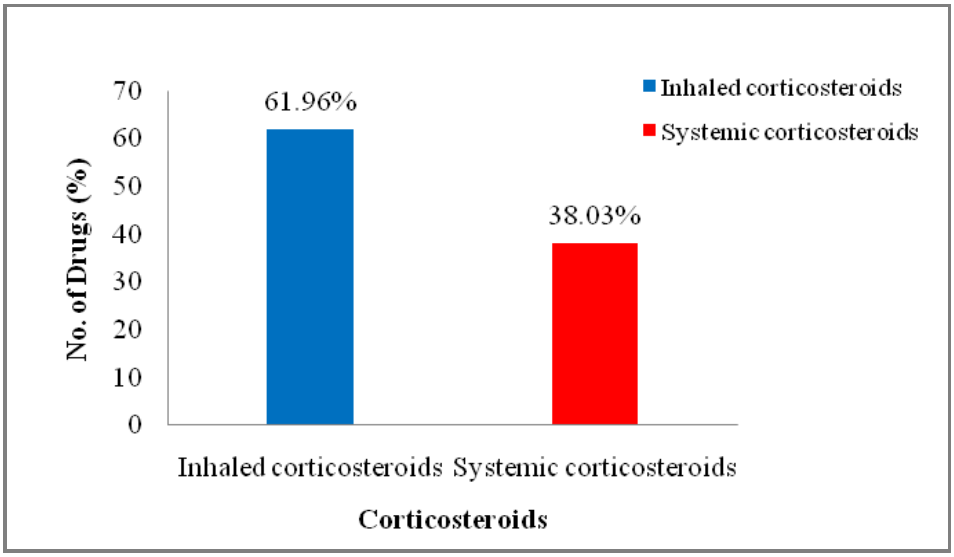

Figure 9: Distribution of prescribed corticosteroids.

- **Most commonly prescribed dosage forms**

Table 10 and Figure 10 showed that oral dosage forms (77.19%), inhalation (14.38%), MDI (8.22%) and topical (0.21%) were mostly prescribed dosage forms.

Table 10: Most commonly prescribed dosage forms.

S. No.	Dosage forms	No. of Drugs (%) (n = 925)
1.	Oral	714 (77.19%)
2.	Inhalation	133 (14.38%)
3.	MDI	76 (8.22%)
4.	Topical	02 (0.21%)

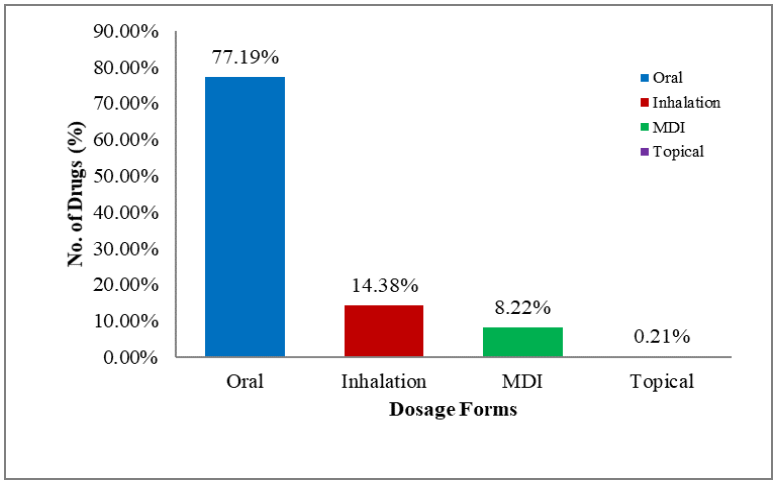

Figure 10: Most commonly prescribed dosage forms.

- **Assessment of single v/s combination drug therapy drugs**

Out of 925 drugs prescribed, 63.02% was prescribed as monotherapy and remaining 36.97% was prescribed as combination therapy. Among monotherapy, 35.02% drugs were prescribed to males and 28% drugs were prescribed to females while among combination therapy, 25.62% drugs were prescribed to males and 11.35% drugs were prescribed to females (Table 11 and Figure 11).

Table 11: Assessment of single v/s combination drug therapy.

S. No.	Drug Therapy	No. of Drugs Prescribed (%) (n = 925)		
		Males	Females	Total
1.	Monotherapy	324 (35.02%)	259 (28%)	583 (63.02%)
2.	Combination Therapy	237 (25.62%)	105 (11.35%)	342 (36.97%)

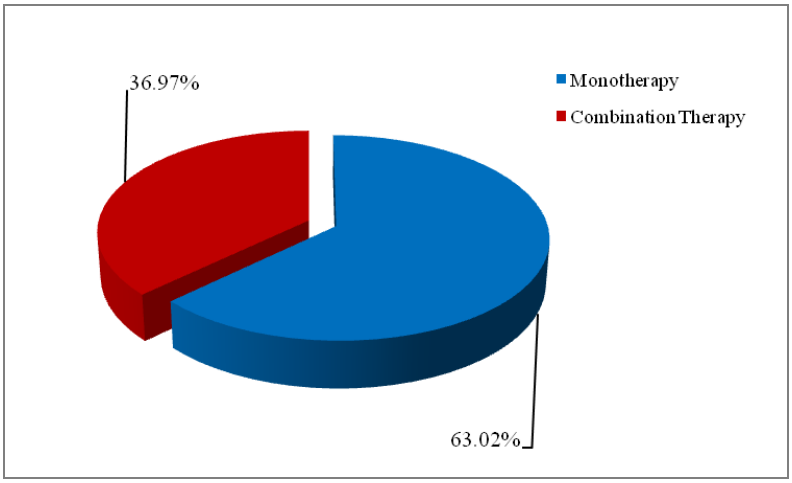

Figure 11: Assessment of single v/s combination drug therapy.

- **Assessment of combination drug therapy**

Table 12 and Figure 12 showed that salbutamol + budesonide (22.5%), theopyllin + etiophyllin (21.66%), salbutamol + ipratropium + budesonide (12.5%), levocetrizine + montelukast (10%), piperacillin + tazobactum (9.16%), ceftriaxone + sulbactam (5.83%), ambroxol + doxofylline (5%), amoxicillin + clavulanic acid (4.16%), salbutamol + ipratropium (3.33%), ipratropium + budesonide (2.5%), salmeterol + fluticasone (1.66%) and formoterol + budesonide (1.66%) were mostly prescribed combination drug therapy.

Table 12: Assessment of combination drug therapy.

S. No.	Combination Drugs	No. of Patients (%) (n = 120)
1.	Salbutamol + budesonide	27 (22.50%)
2.	Theophyllin + etiophyllin	26 (21.66%)
3.	Salbutamol + ipratropium + budesonide	15 (12.50%)
4.	Levocetrizine + montelukast	12 (10.00%)
5.	Piperacillin + tazobactum	11 (9.16%)
6.	Ceftriaxone + sulbactam	07 (5.83%)
7.	Ambroxol + doxofylline	06 (5.00%)
8.	Amoxicillin + clavulanic acid	05 (4.16%)
9.	Salbutamol + ipratropium	04 (3.33%)
10.	Ipratropium + budesonide	03 (2.50%)
11.	Salmeterol + fluticasone	02 (1.66%)
12.	Formoterol + budesonide	02 (1.66%)

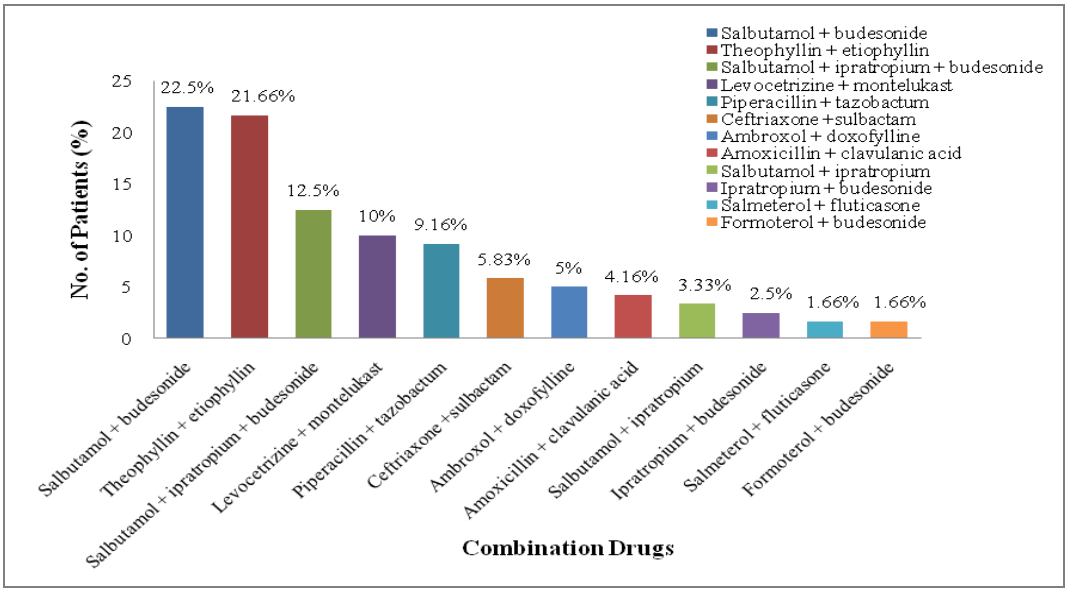

Figure 12: Assessment of combination drug therapy.

- **Average number of drugs per patients**

Table 13 and Figure 13 showed that average number of drugs per patients was found to be 925/120 = 7.70. Maximum number of drugs per patient was 10 among 24.17% patients while least number of drugs per patient was 2 among 1.67% patients. Such greater number of drug use per patients reflects the concept of polypharmacy.

Table 13: Average number of drugs per patients.

No. of Drugs per Patient	No. of Patients (%) (n = 120)
2	02 (1.67%)
3	05 (4.17%)
4	08 (6.67%)
5	09 (7.50%)
6	11 (9.17%)
7	14 (11.67%)
8	17 (14.17%)
9	18 (15.00%)
10	29 (24.17%)
11	07 (5.83%)

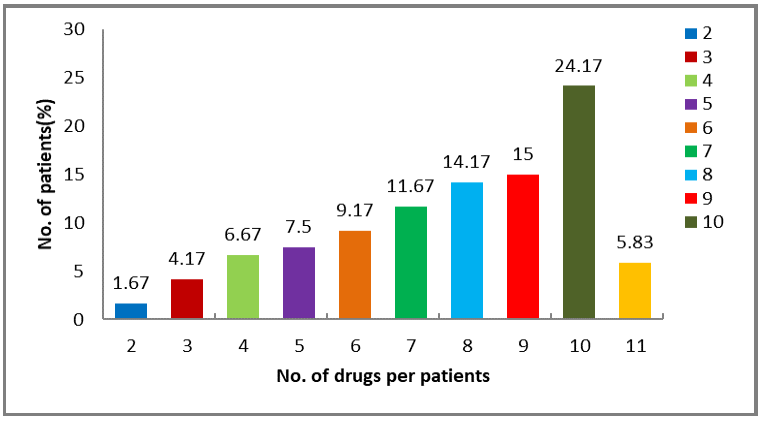

Figure 13: Average number of drugs per patients.

- **Assessment of rationality in drug therapy**

Antibiotics prescribed per encounter were analyzed 18.16% which was high. No irrationality was found, but major patients were found to be over utilized with antibiotic therapy. Antibiotics irrational use is a significant contributor for development of antibiotic resistance among worldwide publics. As antibiotic resistance has posed a significant threat to management of infectious diseases and incidence of antibiotic resistance is increasing day by day, urgent steps are needed to promote rational use of antibiotics During the study it was analyzed that the prescriber was not using any standard antibiotic prescribing guidelines for RTI's not they were following standard guidelines which was available. That's why there is a need of educational programs in order to bring rational use of antibiotics that requires development of standard guidelines for antibiotic prescription.

DISCUSSION

During past few years numerous research studies have been conducted to determine the safe and effective prescription pattern monitoring studies (PPMS) are drug utilization studies with the main focus on prescribing, dispensing and administering of drugs. They promote appropriate use of monitored drugs and reduction of abuse or misuse of monitored drugs. PPMS also guide and support prescribers, dispensers and the general public on appropriate use of drugs, collaborate and develop working relationship with other key organizations to achieve a rational use of drugs. The aim of prescription pattern monitoring studies is to facilitate the rational use of drugs in a population. A prospective observational study was carried out by reviewing prescription of 120 COPD patients. Out of 120 patients 81 (67.5%) were male and 39 (32.5%) were females. The analysis showed that COPD occurs more in men than in women, which get confirmed by demographic results and is largely due to cigarette smoking and other causes can be low

socioeconomic status and occupational exposure to vapor, dust, gas and fumes. This finding is in accordance with results of the previous studies conducted by Unni A et al[5] and Sawant PM et al.[6]

Among the total prescriptions collected, age was taken into consideration by dividing into 7 age groups being kept at interval of 4 years each. The majority of the patients were in age group of 56 - 60 years (34.16%) followed by 51 - 55 years (24.16%), 46 - 50 years (14.16%), 61 - 65 years (9.16%). Age-associated changes in the structure and function of the lung may increase pathogenic susceptibility to COPD and occupational factors can also contribute to COPD. So, risk of developing COPD is more in middle age and elderly patients. Among 120 patients, 79 (65.83%) were smokers, 41 (34.16%) were non-smokers. History of cigarette smoking is the major cause of COPD because cigarette smoke contains harmful toxins that affect the lung functionality and it may leads to stiffening of the air sacs, deterioration of walls between air sacs, thickening and inflammation of the airway walls and increases the production of mucus in the airways, causing air obstruction. It was also observed that 56 (69.13%) were male alcoholics, 02 (5.12%) were female alcoholics. It was also observed that 74 (91.35%) were male smoker, 05 (12.82%) were female smoker. The WHO stated that in 2015, over 1.1 billion people smoked tobacco, males smoked tobacco more than females, and although it is declining worldwide and in many countries, the prevalence of tobacco smoking appears to be increasing in the eastern Mediterranean and Africa.[4]

Etiologic assessment reflected that 68.33% patients were low socioeconomic status followed by exposure to biomass smoker 8.33%. Poverty is consistently associated with airflow obstruction and lower socioeconomic status is associated with an increased risk of developing COPD.[7] 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.[8,9] Due to the incomplete combustion of formaldehyde and DEET, one mosquito coil burning for 8 hour releases the same amount of PM 2.5 as 100 cigarettes. A one hour ‘hookah’ session with ‘shisha’ tobacco is equivalent to smoking over 100 cigarettes.[10]

Out of 120 patients, 64 (53.33%) were not having any other co-morbid condition and the most common co-morbidity found in remaining patients was hypertension 21 (17.5%). Hypertension is frequently seen in COPD patients because of loss of alveolar remodeling of the pulmonary vessels by chronic hypoxia and inflammation, decreases in the levels of endothelial vasodilators such as nitric oxide and vasospasm caused by factors such as endothelin-1. The stress, age, lifestyle modifications may also contribute to hypertension. The result representing hypertension as the mostly found co-morbid condition had similarity with previous studies conducted by Unni A et al.[5] and Sawant MP[6] et al. and Mahmoodan M et al.[11] It was seen that all the prescriptions contained more than 3 drugs which indicates polypharmacy.

A sum total of 925 drugs were used for the management of COPD. Among COPD class of drugs bronchodilators were mostly prescribed 207 (22.38%), which was supported by the results of the previous study conducted by Singh S et al.[12] Bronchodilators are central to the treatment of COPD because they alleviate bronchial constriction and airflow limitation, reduce hyperinflation and improve emptying of the lung and exercise performance. Beta-sympathomimetics 109 (52.65%) is the mostly prescribed drug among bronchodilators. Inhaled corticosteroids 101 (61.96%) are preferred over systemic corticosteroids 62 (38.03%). Systemic bioavailability from the gastrointestinal tract is reduced with inhaled corticosteroids so systemic side effects like hypertension, hyperglycemia etc. can be reduced by the use of inhaled corticosteroids. In COPD patient not receiving inhaled corticosteroids, regular treatment with mucolytics such

as erdosteine, carbocysteine and N-acetylcysteine may reduce exacerbations and modestly improve health status. Due to the heterogeneity of studied populations, treatment dosing and concomitant treatments, currently available data do not allow one to identify precisely the potential target population for antioxidant agents in COPD.[13] Our study showed that beta lactum antibiotics was the mostly prescribed 91 (54.49%) antibiotic and it was supported by the previous studies conducted by the Singh S et al[12] and Kothai R et al.[14] It was found that oral route of administration was mostly used 714 (77.19%) with prescribed drugs in COPD patients with or without co-morbidity, followed by Inhalation 133 (14.38%).

Among Males, 324 (35.02%) were observed monotherapy and 237 (25.62%) were observed combination therapy. On the other hand in females, 259 (28%) were observed monotherapy and 105 (11.35%) were observed combination therapy. This observed that monotherapy is higher as compare to combination therapy which is almost similar to the previous study which revealed 36.97% was combination therapy and 63.02% was monotherapy. In the assessment of combination therapy, we found that salbutamol + budesonide was found that most commonly prescribed (22.5%), followed by Theophyllin + etiophyllin (21.66%), Salbutamol + ipratropium + budesonide (12.5%). The step up in inhaled treatment to LABA plus LAMA plus ICS (triple therapy) can occur by various approaches. This may improve lung function, patient reported outcome and prevent exacerbation, adding a LAMA to existing LABA/ICS improves lung function and patient reported outcomes, in particular exacerbation risk. A double-blind, parallel group, RCT reported that treatment with single inhaler triple therapy had greater clinical benefits compared to tiotropium in patients with symptomatic COPD, FEV1 ≤50%, and a history of exacerbations but double-blind RCT's have reported benefits of single-inhaler triple therapy compared with LABA/LAMA combination therapy.[15,16]

The average number of drugs prescribed per patients was found to be 7.70. WHO recommends that the average number of drugs per prescription should be less than two while in our study this number was found more than two, so it indicates polypharmacy. It is a well established fact that the average number of drugs per prescription value should be low as possible to prevent the unfavorable outcomes of polypharmacy, in this the scale is responsible for more adverse drug reactions, drug interactions and increased cost of treatment, increased risk of drug interactions.

Antibiotics prescribed per encounter were analyzed 18.16% which was high. No irrationality was found, but major patients were found to be over utilized with antibiotic therapy. Antibiotics irrational use is a significant contributor for the development of antibiotic resistance among worldwide publics. As antibiotic resistance has posed a significant thread to management of infectious diseases and incidence of antibiotic resistance is increasing day by day, urgent steps are needed to promote rational use of antibiotics. During the study it was analyzed that the prescriber was not using any standard antibiotic prescribing guidelines for RTI's not they were following standard guidelines which was available. That's why there is a need of educational programs in order to bring rational use of antibiotics that requires development of standard guidelines for antibiotic prescription.[17]

CONCLUSION

This study was conducted with the aim to assess the prescribing pattern of drugs among COPD patients. Bronchodilators, antibiotics, antacids and corticosteroids are most recommended and they also confirm to the rational prescribing practices in the COPD. All the prescription contains more than three drugs indicating polypharmacy and the diagnosis of COPD lacked spirometry. Rational drug utilization needs training of health professionals as per treatment guidelines and prescriber education to ensure appropriate therapy. There is a need of education for both the patients and

the doctors regarding the limited help of antibiotics and other drugs for this self-limiting condition of the patients. Regular studies have been done for the drug prescribing practices so that an appropriate feedback and awareness can be generated among the patients and the health professionals. Moreover, the prescribing patterns reflects the ability of prescriber in terms of choosing those drugs which are accessible, affordable, safe, effective and give maximum benefit to patients. Thus, to ensure the rationality of drug prescription, a time to time monitoring and evaluation is absolutely essential as changes in health related behavior usually take longer to achieve.

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