Assessment of Prescribing Pattern of Corticosteroids and Bronchodilators in the Management of COPD Patients

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ABSTRACT

Introduction: Chronic obstructive pulmonary disease is characterized by chronic airflow limitation and a variety of structural changes in the lung, some severe extra pulmonary consequences, and significant comorbidities that can lead to the severity of the disease in particular patients. Objectives: The objective of the present study was to evaluate prescribing pattern of corticosteroids and bronchodilators in COPD patients and to determine the type of therapy. Materials and Methods: A prospective type of observational study in a 700 bedded multispecialty hospital for 6 months. SPSS (Statistical Package for Social Science) version 20. [IBM SPASS statistics] was used to perform the statistical analysis and to assess prescribing pattern of corticosteroids and bronchodilators in COPD patients. Results: A total of 39 patients were studied. Mean age was 61.4 ± 8.8 with male predominance (82.1%) in comparison to female (17.9%). Majority of the subjects 19 (48.7%) were current smokers, 13 (33.3%) non-smokers, 7 (17.9%) ex-smokers. Hypertension, was found to be the common comorbidity present among the subjects. Combination of Salbutamol and Ipratropium bromide (71.8%) and Antibiotics (71.8%) were the most preferred therapeutic option. It was also observed that combination drugs were used more in comparison to monotherapy. Conclusion: COPD was found to be common in male population compared to females. COPD is more prominent in smokers than non-smokers concluding that smoking is a major risk factor. Combination of Salbutamol and Ipratropium bromide was most frequently prescribed drug followed by antibiotics and budesonide in monotherapy concluding that combination is preferred in the treatment over monotherapy.

Keywords: Chronic Obstructive Pulmonary Disease, Bronchodilators, Corticosteroids, Salbutamol, Ipratropium Bromide, Hypertension, Antibiotics.

INTRODUCTION

COPD is a widespread lung disease characterized by the loss of lung capacity over time.¹ It is a major cause of morbidity and mortality in developed countries, and it is also becoming a major cause of death in developing countries.² The global impact of this respiratory disease is expected to grow.³ COPD is a form of respiratory inflammation that varies from asthma as COPD is a progressive disease while allergic reactions of asthma can be reversible.⁴ According to Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines "Chronic obstructive pulmonary disease is characterized by chronic airflow limitation and a variety of structural changes in the lung, some severe extra pulmonary consequences, and significant comorbidities that can lead to the severity of the disease in particular patients."⁵

Cigarette smoking and occupational exposure were confirmed as high risk factors for COPD and have a higher prevalence of respiratory symptoms and abnormal lung function, a faster annual rate of decline in DOI: 10.5530/ijopp.15.3.33

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Forced Expiratory Volume (FEV1), and a higher COPD mortality rate than nonsmokers.⁶⁻⁷

Pharmacotherapy is used to alleviate symptoms, decrease the incidence and duration of acute exacerbations, delay disease development and death, promote fitness, and increase exercise resistance in patients with stable COPD.8 Treatment can be intensified in stages, depending on the seriousness of the disease. Bronchodilators (selective β2-agonists, anticholinergic antimuscarinic agents, and methylxanthines); glucocorticoids; and other forms of drug (vaccines, antibiotics, 1-antitrypsin augmentation therapy, mucolytic agents, vitamins, immunoregulators, antitussives, and vasodilators) are currently recommended for the management of COPD.9 It is necessary to identify the common risk factors as well as aggressive treatment for COPD with Bronchodilators and Corticosteroids as it have been recommended to help reduce exacerbation of COPD. It also helps COPD patients to delay or prevent progression of the disease or reduce severity of associated complications to sustain and improve patient's quality of life. Non-pharmacological options include everything from training interventions to surgical and bronchoscopic procedures.¹⁰ Non pharmacological therapy is used as an alternative to pharmacological treatment in the early stages of COPD. In terms of patient quality of life and cost-effectiveness, most of these treatment choices prove to be beneficial. Smoking abstinence, rehabilitation, and long-term oxygen treatment are also well recognized as treatments that will help COPD patients control their disease in the long run.11

MATERIALS AND METHODS

The prospective observational study was carried out for a period of 6 months among patients in the Pulmonology and General Medicine department of Yenepoya Medical College Hospital, Mangalore. In-Patients and Out- Patients of both the sex, of above 18 years with or without co morbidities were included. Patients who are below 18 years, patients refusing the consent and the pregnant population were excluded from this study. Demographics of the patients, co morbidities and the prescribing patterns in these patients were reported.

Study site

The study was conducted in the in-patient wards of General Medicine and Pulmonology department in Yenepoya Medical College Hospital, Deralakatte, Mangalore.

Study design: The study was a hospital based prospective and observational study.

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Study period: The study was carried out for a period of 6 months.

Study criteria: The study included patients admitted to the inpatient unit of respiratory department and general medicine due to COPD and patients above the age of 18 years and are willing to give their consent to participate in the study.

Ethical approval: The study was approved by Yenepoya Ethics Committee 2

Approval date: 16-04-2021 Protocol No. YEC2/759

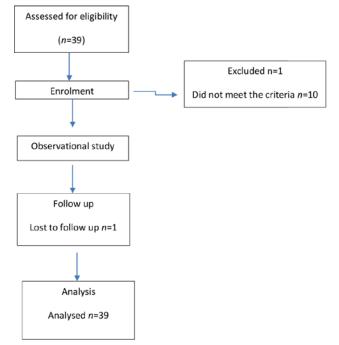
Data collection method

Data will be collected through a review of case sheets in the inpatients of the concerned department. The data collection includes patients details like age, sex, weight, height, history, diagnosis and treatment given to the patients.

Statistical analysis

SPPS (Statistical Package for Social Science) version 20. [IBM, SPASS statistics (IBM CORP, Armonk, NY, USA released 2011)] was used to perform the statistical analysis. Data was entered in the excel spreadsheet. Descriptive statistics of the explanatory and outcome variables were calculated by mean, standard deviation, frequency and charts.

RESULTS Consort Flow Chart



The prospective observational study was conducted for a period of 6 months in Yenepoya Medical College Hospital, Deralakatte, Mangalore. A total of 39 patients having Chronic Obstructive Pulmonary Disease were enrolled in the study.

Gender wise distribution of study participants

Out of 39 patients involved in the study, it was observed that 32 (82.1%) were males and 7 (17.9%) were female as represented in Figure 1.

Descriptive statistics on the age wise distribution of the study participants

Out of 39 participants, majority of them 10 (25.6%) were found to be in the age group of 60- 64 years followed by 7 (17.9%) in the age group 55-59 years, 6 (15.4%) in the age group 70- 74 years, 5 (12.8%) in the age group 50-54 years, 5 (12.8%) in the age group 65-69 years, 3 (7.7%) in the age group 75-79 years, 2 (5,1%) in the age group 45-49 years, 1 (2.6%) in the age group 40-44 years as represented in Figure 2. The mean age of the participants was found to be 61.44 years.

Distribution of the study participants based on the smoking status

Out of 39 study participants, it was observed that majority of the subjects 19 (48.7%) were current smokers followed

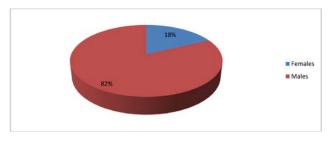


Figure 1: Pie chart representing gender wise distribution of study participants.

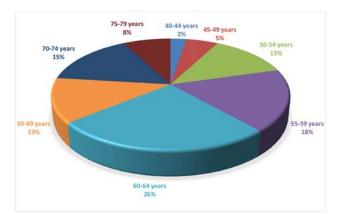


Figure 2: Pie chart representing age wise distribution of study participants.

by 13 (33.3%) were non-smokers followed by 7 (17.9%) were ex-smokers as represented in the Figure 3.

Distribution of subjects based on comorbidities

The present study considered 39 individuals and it was seen that hypertension was present as a common comorbid condition in 20 (51.3%) individuals followed by 18 (46.2%) with other conditions (Chronic kidney disease (CKD), Diabetes milletus, obstructive sleep apnea, alcohol dependence), 13 (33.3%) individuals with Ischemic heart disease (IHD), 5 (12.8%) individuals with Pulmonary tuberculosis (PTB), 3 (7.7%) with cor pulmonale and 2 (5.1%) individuals with anaemia as represented in Figure 4.

Prescription of various drugs among the study participants

Distribution of drugs were studied in 39 patients and among them the bronchodilator combination drug Salbutamol and Ipratropium bromide was seen to be prescribed to majority of the patients 28 (71.8%) and then Antibiotics in 28 (71.8%) of individuals in the management of COPD. This was then followed by the usage of Budesonide in 21 (53.8%) of the patients, Hydrocortisone in 11 (28.2%) patients, combination of Ambroxol, Terbutaline and Guaifenesin in 10 (25.6%) patients, theophylline in 6 (15.4%) patients, tiotropium bromide in 3 (7.7%) participants and finally the drug Salbutamol used individually only in 1 (2.6%) patient. The representation of which is shown Figure 5.

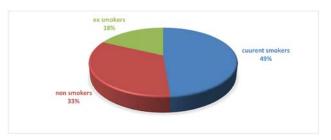


Figure 3: Pie chart representing distribution of the study participants based on smoking status.

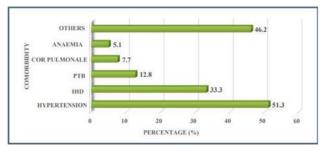


Figure 4: Bar diagram representing distribution of patients based on comorbidities

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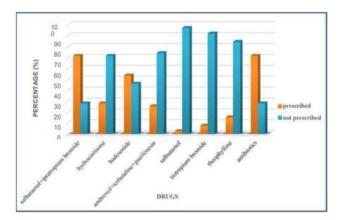


Figure 5: Multiple Bar Diagram representing the prescription of each drug.

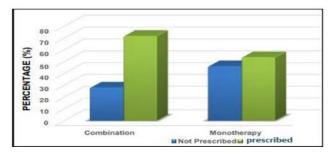


Figure 6: Bar Diagram representing distribution of study participants based on type of therapy.

Distribution of Monotherapy and Combination therapy drugs among the study participants

In this present study it was observed that combination drug was prescribed 71.8% times in comparison to the monotherapy 53.8% as represented in Figure 6.

DISCUSSION

This study was carried out with the aim to analyze the prescribing pattern of bronchodilators and corticosteroids in the management of COPD patients, and also to determine the type of therapy i.e., combination or monotherapy commonly preferred in the management of the disease. The study also aims to determine gender and age distribution in COPD patients as well as to evaluate the most common comorbidity associated in the subjects.

A few short comings of this study are that patients were not randomly selected but were enrolled in the study due to their participation in pulmonary ward and their willingness to give written informed consent. The study's external validity may have been limited by its small sample size, short study period. It is a single center study; validity of findings would increase if it is a multi-centered study. The future perspective of this study could be, to analyze the effects of newer drugs for the treatment of COPD. The study can also be extended to many centers. Pharmacoeconomic evaluation studies can also be done for assessment of COPD management.

The discussion is based on the data obtained from a prospective, observational study that was carried out for a period of 6 months at Pulmonology and General Medicine department of Yenepoya Medical College Hospital, Mangalore after obtaining approval from Yenepoya Ethics Committee. A written informed consent was obtained from 39 patients who were willing to participate in the study considering the inclusion and exclusion criteria. Demographic, clinical and medication details were collected in a specially designed proforma.

Out of the 39 patients included in the study, 32 (82.1%) of the subjects were found to be male and 7 (17.9%) of the subjects were found to be female. The number of male patients suffering from COPD were higher compared to female according to the study. The results were identical to the study conducted by Divya Rekha O *et al.*¹³

In this study, the subjects were separated into eight different age groups namely, 44-45 years, 45-49 years, 50- 54 years, 55-59 years, 60-64 years, 65-69 years, 70-74 years, 75-79 years and the number of patients falling into each group was observed to be 1(2.6%), 2 (5.1%), 5 (12.8%), 7 (17.9%), 10(25.6%), 5 (12.8%), 6 (15.4%), 3 (7.7%) respectively. The mean age group of the patients was learned to be 61.4 years (±8.8). Large number of patients 10 (25.6%) belonged to the age group 60-64 years, this was supported by the study conducted by Shiv Kumar *et al.*¹⁴

The participants were observed based on their smoking status. Study showed that history of smoking was present in 67% of patients including 19 (49%) current smokers, 7 (18%) ex-smokers and it was also seen that 13(33%) were non-smokers. The study was supported by Boggia B *et al.* showing that majority of the subjects had a history of smoking.⁶

Distribution of the study population was done based on the comorbid conditions present. It was observed that maximum of the study participants 20 (51.3%) had hypertension as a common comorbid condition which was then followed by the presence of IHD in 13 (33.3%), PTB in 5 (12.8%), cor pulmonale in 3 (7.7%), Anaemia in 2 (5.1%) and other conditions like CKD, Alcohol dependence, obstructive sleep apnea etc. in 18 (46.2%) of the participants. This data is supported by a study conducted by Mazher Maqsood *et al.* showing that hypertension is the most common comorbidity among the subjects.¹⁵

Distribution of drugs were studied in 39 patients and among them the drug combination of Salbutamol and Ipratropium bromide in 28 patients and Antibiotics in 28 patients were prescribed and was determined to be the main therapeutic option. Budesonide was prescribed to 21 patients (53.8%), Hydrocortisone was prescribed to 11 patients (28.2%), combination of Ambroxol, Terbutaline and Guaifenesin was prescribed to 10 patients (25.6%), followed by theophylline in 6 patients (15.4%), tiotropium bromide in 3 patients (7.7%) and salbutamol in 1 patient (2.6%). The participants were also distributed based on the type of therapy received by them. It was observed that combination drug was prescribed 71.8% times in patients in comparison to the monotherapy given 53.8% of the times. It clearly shows that combination therapy was preferred in the treatment over monotherapy.

CONCLUSION

The present study involved 39 participants with Chronic Obstructive Pulmonary Disease and it was observed that this condition was majorly found in the male population as compared to the females (82% males and 18% females). Majority of the patients were from the age group 60-64 years, the mean age being 61.4 years. COPD is more prominent in smokers than the nonsmokers concluding that smoking is a major risk factor of developing the condition. In our study it was seen that Hypertension was the most common comorbidity among the participants. The study demonstrates that the combination of Salbutamol and Ipratropium bromide was most frequently prescribed drug followed by antibiotics and budesonide in monotherapy which clearly shows that the combination therapy was preferred in the treatment in comparison to the monotherapy.

CONFLICT OF INETREST

The authors declare no conflict of interest.

ABBREVIATIONS

COPD: Chronic Obstructive Pulmonary Disease; **FEV:** Forced Expiratory Volume; **FVC:** Forced Vital Capacity; **GOLD:** Global Initiative for Chronic Obstructive Lung Disease; **PTB:** Pulmonary Tuberculosis.

REFERENCES

- Wells BG, Dipiro JT, Schwinghammer TL, Dipiro CV. Pharmacotherapy handbook. 9th ed. MCGraw-Hill Education; 2015. Chronic obstructive pulmonary disease. p. 835-43.
- Fazleen A, Wilkinson T. Early COPD: Current evidence for diagnosis and management. Ther Adv Respir Dis. 2020;14:1753466620942128. doi: 10.1177/1753466620942128, PMID 32664818.
- Viegi G, Scognamiglio A, Baldacci S, Pistelli F, Carrozzi L. Epidemiology of chronic obstructive pulmonary disease (COPD). Respiration. 2001;68(1):4-19. doi: 10.1159/000050456, PMID 11223724.
- Laurence L, Bruce A. Chapter 36, Pulmonary pharmacology. Bjorn C. Goodman and Gilman'sthe pharmacological basis of therapeutics. 12th ed. McGraw-hill companies; 2011. p. 1031-64.
- Koda-Kimble MA. Chapter 24. Chronic obstructive pulmonary disorder. In: Koda-Kimble and Young's applied therapeutics: The clinical use of drugs. 10th ed. Lippincott Williams and Wilkins; 2012. p. 601-24.
- Boggia B, Farinaro E, Grieco L, Lucariello A, Carbone U. Burden of smoking and occupational exposure on etiology of chronic obstructive pulmonary disease in workers of Southern Italy. J Occup Environ Med. 2008;50(3):366-70. doi: 10.1097/JOM.0b013e318162f601, PMID 18332787.
- Kohansal R, Martinez-Camblor P, Agustí A, Buist AS, Mannino DM, Soriano JB. The natural history of chronic airflow obstruction revisited: An analysis of the Framingham offspring cohort. Am J Respir Crit Care Med. 2009;180(1):3-10. doi: 10.1164/rccm.200901-0047OC, PMID 19342411.
- Antus B. Pharmacotherapy of chronic obstructive pulmonary disease: A clinical review. ISRN Pulmonol. 2013;2013:1-11. doi: 10.1155/2013/582807.
- Montuschi P. Pharmacological treatment of chronic obstructive pulmonary disease. Int J Chron Obstruct Pulmon Dis. 2006;1(4):409-23. doi: 10.2147/ copd.2006.1.4.409, PMID 18044097.
- Mulhall P, Criner G. Non-pharmacological treatments for COPD. Respirology. 2016;21(5):791-809. doi: 10.1111/resp.12782, PMID 27099216.
- Clini E, Costi S, Lodi S, Rossi G. Non-pharmacological treatment for chronic obstructive pulmonary disease. Med Sci Monit. 2003;9(12):RA300-5. PMID 14646985.
- Vogelmeier CF, Criner GJ, Martinez FJ, Anzueto A, Barnes PJ, Bourbeau J, et al. Global strategy for the diagnosis, management, and prevention of chronic Obstructive lung disease 2017 report. Gold executive summary. Am J Respir Crit Care Med. 2017;195(5):557-82. doi: 10.1164/rccm.201701-0218PP, PMID 28128970.
- Rekha D, Jaya Preethi P, Saravanakumar K, Swetha A. Prescribing patterns of drugs in chronic obstructive pulmonary disease- in a tertiary care teaching hospital. J Glob Trends Pharm Sci. 2019;10(4):7125-30.
- Kumar S, Madhuri G M, Wilson A, George TS Study of Prescribing Pattern of Drugs in Chronic Obstructive Pulmonary Disease in Tertiary Care Teaching Hospital. IJOPP. 2019;12(3):161-6. doi: 10.5530/ijopp.12.3.36.
- Maqusood M, Ahmad F, Khan MK. A study of prescription pattern in the management of COPD in a tertiary Care Hospital. Ann Int Med Den Res. 2016;2(3):159-63.