A Study of Prescription Pattern in the Management of COPD in a Tertiary Care Hospital.

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ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is a common preventable and treatable condition characterized by persistent airflow obstruction that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Bronchodilators are mainstay of pharmacologic management of COPD and Inhaled corticosteroids (ICS) are the central of treatment of asthma but in management of COPD their role is controversial. Aim &Objectives: The sole aim and objective of this study is to evaluate the current prescription pattern of COPD management using data generated in a tertiary care hospital of UP India.. Methods: : In this prospective study, all patient data relevant to the study were obtained by examination of Case sheets of inpatients visiting the OPD of TB & Chest department. Results: In this prospective study, prescriptions of 74 patients were selected. Out of total patients, 60 (81.08%) were males and 14(18.9%) were females. Out of total 74 patients, 73 (98.64%) are smokers, in which 30 (40.54%) are currently smoking while 43(58.1%) are ex-smokers. Out of total patients 60(81.08%) have comorbidities. Hypertension is most common comorbidity having 36 (48.65%) of patients. Inhalational route was most common route of administration of drugs in the study. Oral route was second most common route; it was used for administration of 42.03% of drugs. Formoterol was maximum prescribed drug used in 60 (81.09%) of patients followed by Budesonide 57 (77.03%), Acebrophylline 48 (64.86%), followed by Levocetrizine 41 (51.41%), Salbutamol and Montelukast were used in equal no. of patients 40(54.06%), followed by Ipratropium 39 (52.70%), Tiotropium which was used in 29 (39.19%) of patients, followed by Amoxicillin 16 (21.63%) followed by Theophylline and Azithromycin used in 8 (10.81%) patients ,followed by Doxophylline and Terbutaline which were also used in equal number and percent of patients that is 3 (4.05%). Conclusion: The prescribing trend observed in the study appears to be in concordance with the current GOLD guidelines for the management of COPD patients.

Keywords: COPD, Bronchodilators, Anti-Histaminics.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a common, preventable and treatable condition characterized by persistent airflow obstruction that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases.^[1]

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The chronic airflow obstruction that is characteristic of COPD is caused by a mixture of small airway disease (chronic bronchitis) and destruction of lung parenchyma (emphysema), the relative contribution of which vary from patients to patients. Chronic inflammation leads to structural changes and narrowing of the small airways. In COPD pharmacotherapy is given to reduce symptoms, reduce frequency and severity of exacerbations, improve health status and exercise tolerance.^[1] Bronchodilators are the mainstay of pharmacological management of COPD.^[1] Short acting bronchodilators are given for immediate relief from symptoms, one or more long acting bronchodilators

(long acting beta 2 agonist [LAβAs]) or long acting muscarinic antagonist [LAMAs] are used for long term maintenance treatment in subjects with moderate to severe disease.[1-3] Inhaled corticosteroids (ICS) are the central of treatment of Asthma but in the management of COPD their role is controversial.[4-7] In COPD, the role of ICS is primarily to decrease the risk of exacerbations.[8] The new GOLD strategy recommends the addition of second bronchodilator in patients with moderate airflow obstruction, reserving the ICS use in addition with a LABA and /or LAMA for patients with severe or very severe airflow obstruction and /or two or more exacerbations of COPD per year.[1] But there is evidence that prescriptions are not always written according to GOLD recommendations or other national guidelines^[5,9-14], resulting in a high proportion of patients being treated with ICS unnecessarily and exposed to the risk of side effects in undue manner.

The objective of this study is to evaluate the current prescription pattern of COPD management using data generated in a tertiary care hospital of UP India

MATERIALS AND METHODS

Study place: It was a prospective study conducted in the outpatient Department of TB& chest in collaboration with the Department of Pharmacology,

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Teerthanker Mahaveer Medical College& Research Center, Moradabad UP India.

Study design: It is a prospective, observational and hospital based study.

Study period: The study was conducted in a 9 month period.

Study group: Patients with a diagnosis of COPD visiting TB& Chest department.

Data was collected from

- Case sheets of inpatients visiting the OPD of TB& Chest department
- 2. OPD card of the out patients.

Patients were enrolled on the basis of inclusion and exclusion criteria.

The prescriptions of patients were analyzed by the following parameters in a specially designed data collection forms.

- 1. Demographic data of the patient.
- 2. Category of the drug used in the treatment.
- 3. Type of therapy- Mono therapy or combination therapy

RESULTS

Demographic details

This is a prospective study in which prescriptions of 74 patients were selected on the basis of inclusion and exclusion criteria. Among 74 patients, 60 (81.08%) were males and 14(18.9%) were females. The mean age of patients is 55.95 years [Table 1]. Male: Female ratio is 4.2:1. Out of total 74 patients, 73 (98.64%) are smokers in which 30 (40.54%) are currently smoking while 43 (58.1%) are ex-smokers [Table 2]. Out of total patients 60 (81.08%) have comorbidities. Hypertension is most common comorbidity having 36 (48.65%) of patients.

Routes of Drug Administration

Inhalation route (56.46%) was the most common route of administration of drugs in this study followed by Oral route (42.03%) was the second most common route and Parenteral route (1.51%) was the least used route.

Drug utilization pattern [Table 3]

In Total 74 patients, Formoterol was maximum prescribed drug, n= 60 (81.09%) followed by Budesonide n=57 (77.03%), Acebrophylline 48 (64.86%), Levocetrizine 41 (51.41%), Salbutamol and Montelukast were used in equal no. Of patients n=40 (54.06%), followed by Ipratropium 39 (52.70%), followed by Tiotropiumn= 29 (39.19%) of patients, Amoxicillinn = 16 (21.63%), Theophylline and Azithromycin used in 8 (10.81%) patients, followed by Doxiphylline and Terbutaline which were also used in equal number and percent of is 3 (4.05%). that Fluticasone, Methylprednisolone and Hydrocortisone were least prescribed drugs used in equal number and percent 2

(2.70%) of patients. Only 4 (5.40%) patients were immunized with Influenza vaccine.

When we evaluate the different classes of drugs used in the therapy we found that Beta-2 agonists were most frequently used class of drug an average followed by Anti-muscarinics n=68 (91.89%) of patients, Inhaled corticosteroids and Phosphodiesterase inhibitors which were used equally in 59 (79.73%) of patients. It was followed by Antihistamine n=41 (55.40%) and Leukotriene receptor antagonistm=40 (54.05%), followed by Antibiotics which were used in n=24 (32.43%) of patients. Systemic corticosteroids were least used only in 4 (5.40%) of patients [Table 4].

Mono therapy was given to only 1 (1.35%) of patients in the entire study while the combination therapies were given to all remaining patients.

Total 31 different combinations are used in whole study. The most frequently used combination in the study was Budesonide + Acebrophylline + Formoterol + Salbutamol + Ipratropium + Montelukast + Levocetrizine + Antibiotic that was used in 19 (25.67%) of patients. The second most frequently used combination was Budesonide + Formoterol + Tiotropium + Acebrophylline + Montelukast + Levocetrizine that was used in 5 (6.75%) patients. The third most frequently used combination was Budesonide + Formoterol + Salbutamol + Ipratropium + Acebrophylline, which was used in 4 (5.4%) patients. Other combinations used in the study were given in [Table 5].

Table 1: Demographic table showing age and gender distribution of COPD patients.

Age(Years)	Male N (%)	Female N (%)	Total no. of patients
30-39	1(1.35%)	1(1.35%)	2(2.7%)
40-49	13(17.57%)	9(12.17%)	22(29.73%)
50-59	21(28.38%)	2(2.7%)	23(31.09%)
60-69	18(24.33%)	1(1.35%)	19(25.67%)
70-79	7(9.46%)	0	7(9.46%)
80-89	0	1(1.35%)	1(1.35%)
TOTAL	60(81.09%)	14(18.91%)	74

Table 2: Showing smoking status of the patients.

Smoking Status	No Of Patients	Percentage
Smokers	73	98.64
Ex-smokers	43	58.1
Current smokers	30	40.54
Non Smokers	1	1.36

Table 3: Showing details of Routes used in administration of drugs.

Routes	No. of drugs	Percentages
Inhalational	227	56.46
Oral	169	42.03
Injection	6	1.51

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Table 4: Drugs Prescribed in COPD patients.

Groups of Drugs	Drugs	No. of patients	Percentages	Routes of
				administration
	Formoterol	60	81.08%	Inhalational
β_2 Agonists	Salbutamol	40	54.05%	Inhalational
	Terbutaline	3	4.05%	Oral
Antimuscarinics	Tiotropiam	29	39.18%	Inhalational
	Ipratropiam	39	52.70%	Inhalational
Inhaled Corticosteroids	Budesonide	57	77.02%	Inhalational
	Fluticasone	2	2.70%	Inhalational
Phosphodiesterase Inhibitors	Acebrophylline	48	64.86%	Oral
	Theophylline	8	10.81%	Oral
	Doxiphylline	3	4.05%	Oral
Leucotrine receptor antagonist	Montelukast	40	54.05%	Oral
Antihistamines	Levocetrizine	41	55.40%	Oral
Vaccine	Influenza Vaccine	4	5.40%	Injection
	Amoxicillin &Clavulanic	16	21.63%	Oral
Antibiotics	acid			
	Azithromycin	8	10.82%	Oral
Systemic corticosteroids	Methylprednisolone	2	2.70%	Oral
	Hydrocortisone	2	2.70%	Injection

Combinations Of Drugs Used In COPD Patients	Frequency	Percentages
For moterol + salbutamol + Budesonide + Iprotropiam + Acebrophylline + Montelukast + Levocetirizine + Antibiotic - Antib	19	25.67
Formoterol+Budesonide+Tiotropiam+Acebrophylline+Montelukast+Antibiotic	2	2.7
Salbutamol+Ipratropiam+Acebrophylline+Antibiotic+Hydrocortisone	1	1.35
Formoterol+Acebrophylline+Montelukast+Antibiotic+Hydrocortisone	1	1.35
Salbutamol+Iprotropiam+Acebrophylline+Montelukast+levocetirizine+Antibiotic+Methylprednisolone	1	1.35
Tiotropiam+levocetirizine+Montelukast+Acebrophylline+Antibiotic+Methylprednisolone	1	1.35
Salbutamol+Ipratropiam+Budesonide	1	1.35
Salbutamol+Fluticasone+Ipratropiam+Doxyphylline+Montelukast+Levocettirizine+Anbio	1	1.35
Budesonide+Formoterol+Tiotropiam	1	1.35
Budesonide+Formoterol+Salbutamol+Ipratropiam+Acebrophylline	4	5.41
Acebrophylline+Montelukast	1	1.35
Acebrophylline+Budesonide+Formoterol+Tiotropiam+Salbutamol+Antibiotic	2	2.7
Budesonide+Formoterol+Salbutamol+Ipratropiam+Montelukast+Levocetirizine+Antibiotic	2	2.7
Salbutamol+Iprotropiam+Fluticasone+Levocetirizine+Acebrophylline	1	1.35
Budesonide+Formoterol+Salbutamol+Iprotropiam+Acebrophylline+Levocetirizine+montelukast	2	2.7
Budesonide+Fmoterolor+Tiotropiam+Theophylline+InfluenzaVaccine+Antibiotic	1	1.35
Tiotropiam+Theophylline	2	2.7
Budesonide+Formoterol+Salbutamol+Iprotropiam	3	4.06
Formoterol+Budesonide+Salbutamol+Acebrophylline+Levocetirizine+Montelukast	2	2.7
Budesonide+Formoterol+Salbutamol+Iprotropiam+Acebrophylline+Levocetirizine	3	4.6
Budesonide+Formoterol+Salbutamol+Iprotropiam+Montelukast	1	1.35
Budesonide+Formoterol+Salbutamol+Montelukast+Levocetrizine	1	1.35
Budesonide+Formoterol+Tiotropiam+Acebrophylline+Montelukast+Levocetirizine	5	6.75
Tiotropiam	1	1.33
Tiotropiam+Acebrophylline+Levocetirizine	2	2.7
Budesonide+Formoterol+Tiotropiam+Acebrophylline+Levocetirizine	2	2.7
Tiotropiam+Formoterol+Acebrophylline	1	1.35
Formoterol+Theophylline+InfluenzaVccine	1	1.35
Budesonide+Formoterol+Tiotropiam+Salbutamol	3	4.06
Formoterol+Budesonide+Tiotropiam+Acebrophylline	2	2.7
Tiotropiam+Theophylline+Influenza Vaccine	2	2.7
Budesonide+Formoterol+Terbutaline+Tiotropiam+Theophylline	1	1.35

DISCUSSION

Based on the result of the present study, mean age of the total COPD population is 54.6 years, which is not accordance with the study done by David price (2014) Which showed that the mean age of the total COPD population was 71.4 years^[15] and also not

accordance with CAGE study (2008) in which the mean age of COPD population was 69.9 years.[16] It is also not accordance with Melissa H. Robert has studied (2013) in which mean age of the total COPD population 69 years. It is because of life span relatively less in India. According to the present study, 81.09% patients were male, while David price study 2014. 53% patient were male^[15] CAGE study (2008). 60% patient were male^[16] so it is not accordance with the present study. This variation is because of smoking is more common among male than female in India. But it is accordance with the study of Arya Gigi (2015) who reported that 78% patient were male.^[17] But not in accordance with Melissa H. Robert study which shows that 42% patient were males. Present study^[1] shows that 98.64% patient were smokers which is close to Arya Gigi study 2015 according to which 100% patient were smokers.^[17] The present study shows that 58.1% patients are ex-smokers, which is near to the David price study (2014) which shows that 56.2% patients were ex-smokers. ^[15]

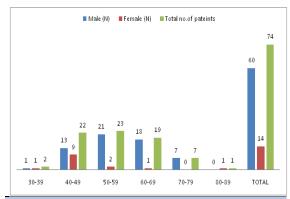


Figure 1: Showing age and gender distribution of COPD patients.

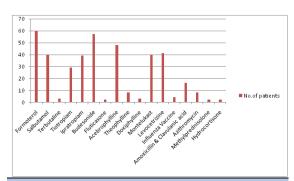


Figure 2: Showing drugs prescribed in COPD patients.

This study also shows that 40. 54% patients were still smoking, which is accordance with CAGE study (2008) which showed that 40% of patients were current smokers.^[16] In the present study, 81.08% of patients have co-morbidities, which is close to CAGE study (2008) which shows that 81.08% of patients had co-morbidity. [16] Present study shows that 73.72% of patients have received inhaled corticosteroids while in CAGE (2008) study 67% [16] and David price study (2014) 60% patients had received ICS [15] so these are not accordance with the present study. In the present study Tiotropium is used in 39.18% of patients which is near to David price study (2014) in which it was used in 34.6% of patients^[15] and also near to the marc mirravitles (2007) study in which it was used in 32.4% of

patients. In the present study, Formoterol is used in 81.08% of patients, which is not accordance with David price study (2014) in which it was used in 54.6% of patients.^[15] SABA's are used in 51.1% of patients in the present study it is not accordance with David price study (2014) in which they were used only in 11.8% of patients.^[15] In the present study, ipratropium was used in 52.7 of the patients, which is not accordance with David price study (2014) in which it was used only in 2.1% of patients.[15] In the present study methylxanthines are used in 79.72% of patients while in Arya Gigi study 2015 they were used in only 19% of patients^[17] so it is not accordance with the present study. In Arya Gigi study (2015) doxofylline was mostly prescribed Methylxanthine (56.89%), this is not accordance with the present study in which it was last prescribed, here at cebrophyline was mostly prescribed Methylxanthines. In the present study, antibiotics are used in 32.43% of patients. It is not accordance with Arya Gigi study (2015) in which these are used in 42% of patients.^[17] In the present study, Amoxicillin is most prescribed antibiotics it is not accordance with Arya Gigi study (2015) in which ceftriaxone was most prescribed antibiotics. Azithromycin is second most prescribed antibiotic in the present study it is accordance with Arya Gigi study in which it was also second most prescribed antibiotic. [17] In the present study influenza vaccine are used in only 5.40% of patients .it is not accordance with CAGE (2008) study in which they were used in 80% of patients.^[16] In the present study, Montelukast was used in 54.05% of patients it is not accordance with David price study in which it was used in 2.1% of patients.^[15] it is not accordance with CAGE study also in which it was not used. Antihistamine is used in 55.40% of patients in present study it is not accordance with David price and CAGE where it was not used. In David price study (2014) ICS+LABA (26.7%) was most frequently used combination.[15] While in CAGE study LABA + LAMA (32%) was most frequently used combination^[16] and in Arya Gigi study SABA + SAMA +ICS was most frequently used combination, these are not accordance with the present study in which **ICS** +SABA+SAMA + Methylxanthines Antihistamines + LTRA + Antibiotics (25.67%) was most frequently used combination of drugs. In the present study 88.69% of drugs are written with their trade name and 11.31% drugs are written with their generic name it is accordance with Arya Gigi studied in which it 89% drugs were written trade name and 11% are written in generic name.[17] Second, most frequently used combination in Devid price study was ICS + LABA +LAMA (15)it is not accordance with the present study in which ICS+Methylxanthine +LABA+LAMA+LTRA+Antihistamines. In CAGE study (2008) separate smoking cessation counselling was given to 95% of patients.[16] These

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findings were not in accordance with the present study in which it is not given to any patients. In a CAGE study (2008) 9% of patients were referred for pulmonary rehabilitation^[16] it also not accordance with the present study in which no patients are referred to this. In the present study, the most preferred route of administration is inhalation. It is not accordance with AryaGigi study in which most preferred route of administration was oral.[17] It is seen in the present study of drugs (79.85%) are prescribed according to the GOLD (a global initiative of obstructive lung disease) criteria recommendation.^[1] In some cases, the discordance between GOLD treatment recommendation and day to day clinical practice is normal because of difference individual patient needs and co-morbidity this is supported NICE guidelines which advocates that individual needs and should be taken into account while prescribing.

CONCLUSION

It was found in the study that majority of prescriptions were prescribed according to GOLD recommendations a large proportion of patients left the treatment later because of their financial reasons. This study also show that prescription of generic drugs is very low and it is known that financial burden of patients can be reduced up to some extent by promoting generic prescription, so this study suggests that effort must be done to encourage generic prescription.

This study also shows that despite of advice to stop smoking a large proportion of patients are still smoking so a separate smoking cessation counselling may help to overcome this problem which are not conducted in the present study.

In the present study vaccination was given to very little number of patients so it should also be promoted as per GOLD recommendations. In the entire study no patient was referred for pulmonary rehabilitation so it should also be promoted in appropriate patients as per GOLD recommendation.

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