Original Research Article

Drug utilization study of drugs prescribed in patients suffering from chronic obstructive pulmonary disease attending the pulmonary medicine outpatient department of a tertiary care hospital-an observational study

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ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is a progressive respiratory disorder requiring long-term pharmacological management. This study aimed to evaluate prescription patterns, drug utilization, polypharmacy and cost analysis in COPD patients attending the outpatient department of a tertiary care hospital.
Methods: This single-center, cross-sectional observational study was conducted in collaboration with the Department of Pulmonary Medicine. A total of 600 prescriptions of COPD patients were analyzed over 18 months (January 2020–June 2021) following WHO guidelines for Drug Utilization Studies. Adult patients diagnosed with COPD and attending the outpatient department were included. Data on demographics, drug classes, fixed-dose combinations (FDCs), essential drug listing and cost burden were collected and analyzed using descriptive statistics.
Results: The average age of patients was 62.87±14.52 years, with 84.67% being male. A total of 3815 drugs were prescribed, with bronchodilators (62.70%) being the most common class, followed by corticosteroids (8.10%). Tiotropium bromide and Salbutamol were the most frequently used individual drugs. The average number of drugs per prescription was 6.36±2.31, indicating polypharmacy. Fixed-dose combinations such as Theophylline+Etophylline (41.87%) were commonly prescribed. The average prescription cost was 647.23 INR, of which 44.90% was borne by patients. Most drugs (69.78%) were prescribed by generic names and 62.43% were from the National Essential Medicines List.
Conclusions: This study highlights a significant degree of polypharmacy and suggests that while prescribing trends largely align with GOLD guidelines, greater access to essential drugs through hospital pharmacies and efforts to reduce patient cost burden are warranted.

Keywords: Bronchodilators, Corticosteroids, COPD, Drug utilization

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a life-threatening lung condition characterized by persistent airflow obstruction due to small airway disease (chronic bronchitis) and lung parenchyma destruction (emphysema).[1,2] Chronic bronchitis leads to excessive mucus production and airway inflammation, while emphysema results in alveolar damage, causing airflow limitation. COPD is projected to be the 3rd leading cause

of death by 2030, with prevalence ranging from 6.5%-7.7% in rural India and up to 9.9% in urban areas.[3] It remains a significant burden on healthcare, contributing to over 3 million deaths in 2012, with 90% occurring in low- and middle-income countries.[4] Unless urgent measures are taken, COPD-related mortality may increase by 30% in the next decade.[5] Major risk factors include smoking, occupational exposure and genetic predisposition, with COPD prevalence at 5.0% in Indian males and 3.2% in females above 35 years.[6] Pharmacotherapy primarily aims to alleviate symptoms, reduce exacerbations and improve quality of life. Bronchodilators, including short-acting and long-acting beta-2 agonists (LABAs) or muscarinic antagonists (LAMAs), form the backbone of treatment. Inhaled corticosteroids (ICS) are mainly reserved for severe cases with frequent exacerbations.[7]

According to WHO, drug utilization refers to the marketing, distribution, prescription and use of drugs in a society, with implications for medical, social and economic outcomes.[8] Inappropriate drug use leads to resistance, adverse effects and increased healthcare costs, making drug utilization studies essential for evaluating healthcare systems.[9] Rational drug use ensures optimal therapeutic outcomes while minimizing risks and economic burden.[10] However, overprescription, polypharmacy and irrational prescribing remain challenges.[11,12] Studies have shown that β-agonists and anticholinergics play a key role in COPD management, while steroids and methylxanthines also have significant use.[7,13] Despite COPD being a leading cause of death in India, drug utilization studies remain limited. This study aims to assess prescribing patterns, ensuring appropriate drug use and understanding factors influencing therapeutic decisions in COPD management.

Aims and objectives

Primary objectives

To identify pattern of drug prescribed for management of COPD patients attending outpatient department. To delineate the various drugs given in COPD and their classes used in the management of COPD. To assess the degree of poly pharmacy. Drug cost analysis of drug prescribed for management of COPD patients in a tertiary care hospital.

Secondary objectives

To identify the limitations in drugs prescribed in COPD patients and suggest recommendations for rational drug prescriptions in patients attending outpatient department, if possible. To assess the implication of drug prescribed for any concomitant conditions if any.

METHODS

This single-center, cross-sectional, observational study was conducted in the Department of pharmacology in collaboration with the pulmonary medicine OPD at a tertiary care hospital to evaluate COPD drug prescription patterns. A total of 600 prescriptions were analyzed over 18 months (January 2020–June 2021) following WHO recommendations for drug utilization studies (DUS).[14] Ethical approval was obtained from the Institutional Ethics Committee (IEC). Patients aged >18 years with a COPD diagnosis and prescribed COPD medications were included, while those <18 years, pregnant women, unwilling participants, inpatients and those with life-threatening conditions were excluded. Data, including patient demographics, diagnosis, prescription details, drug classes and cost analysis, were compiled in Microsoft Excel and analyzed using descriptive statistics, with continuous variables presented as Mean±SD and categorical variables as percentages.

RESULTS

In demographic characteristics, it was found that the average age of the study population was 62.87±14.52 years. Majority of the participants, 243 (40.50%) were in the age group of 61-70 years (Table 1). 508 (84.67%) were males and 92 (15.33%) were females. The percentage of males was greater than that of females. The age group of 61-70 years had the maximum number of patients (243) with 185 (36.42%) males and 58 (63.04%) females (Figure 1). Majority of the study population 340 (56.67%) belonged to the Hindu religion. Majority of the participants, 242 (40.33%) were having weight in the weight group of 61-70 Kgs. Out of 600 study participants, 300 (50%) Participants were having weight less than 60 Kgs. The socio-economic distribution of the study population was evaluated in accordance with the modified Kuppuswamy socio-economic status scale. It was found that the maximum of the population in whom drugs for COPD were prescribed belonged to the upper-lower status–399 (66.50%). Majority of the study population were from the district wise division of Konkan: 510 (85%). A maximum patients 346 patients (57.67%) were unemployed. The majority of the participants, 260 (43.33%) were smokers (Table 2).
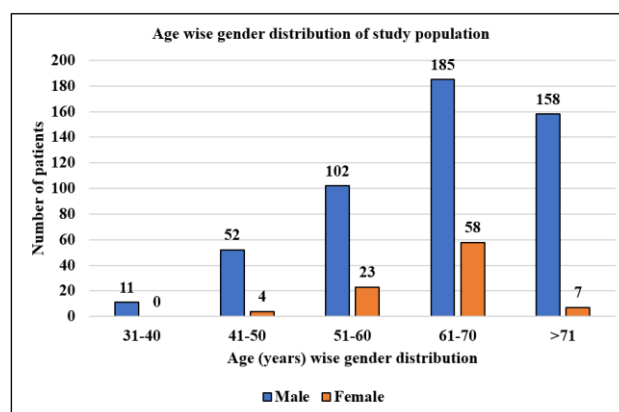

Figure 1: Age wise gender distribution of study population (n=600).

**Table 1: Age distribution of the study population (n=600).**

Age (years)	Number of patients	Percentage (%)
31-40	11	1.83
41-50	56	9.33
51-60	125	20.83
61-70	243	40.50
>71	165	27.50
Total	600	100

**Table 2: Smoking Status of the study population (n=600).**

Smoking status	Number of patients	Percentage (%)
Smokers	260	43.33
Ex-smokers	129	21.50
Non-smokers	211	35.17
Total	600	100

Table 3: Comorbid status of study population (n=600).

Co-morbidity	Number of patients	Percentage (%)
No Co-morbidity	347	57.83
Hypertension	136	22.67
Ischemic heart disease	32	5.33
Diabetes	20	3.33
Osteoarthritis	33	5.50
Cerebrovascular accident	7	1.17
Epilepsy	6	1.00
Chronic kidney disease	3	0.50
Hypothyroidism	3	0.50
Tinea corporis	9	1.50
Seborrheic dermatitis	4	0.67
Total	600	100
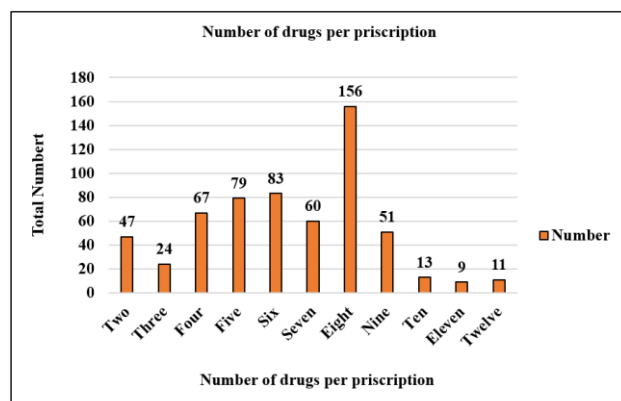
Figure 2: Analysis of the number of drugs prescribed in each prescription (n=600).
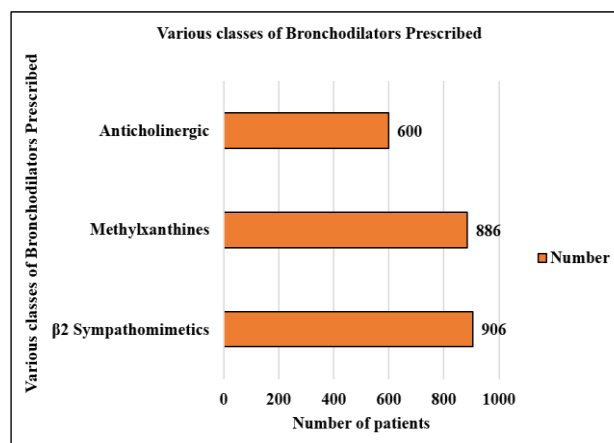
Figure 3: Analysis of the various classes of Bronchodilator prescribed in the study population (n=2392).

When patients were studied for other co-morbidities, the majority i.e., 347 (57.83%) patients, were not associated with any other co-morbidity. The most common co-morbidity associated with COPD was Hypertension, 136 (22.67%) (Table 3). A total of 3815 drugs were prescribed in our study population, considering drugs in FDC as a separate and individual drug, out of which 2392 (62.70%) were Bronchodilators, 309 (8.10%) were Corticosteroids (Table 4). The minimum drugs per prescription was 2 in 47 such patients and the maximum drugs per prescription encountered was 12 in 11 such patients (Figure 2). The average number of drugs prescribed per prescription in the study population was 6.36±2.31 whereas the average number of drugs prescribed for COPD per prescription in the study population was 4.50±1.42. In the present study, out of the 2701 drugs prescribed in the study population, 2392 (88.56%) of them belonged to Bronchodilators group and 309 (11.44%) belonged to the Corticosteroids group. Among the Bronchodilators, the β2–Sympathomimetic subgroup 906 (37.88%) is the more common one to be prescribed in the study population (Figure 4). Among the β2–Sympathomimetic, the Salbutamol 582 (64.24%) is prescribed more common in the study population.
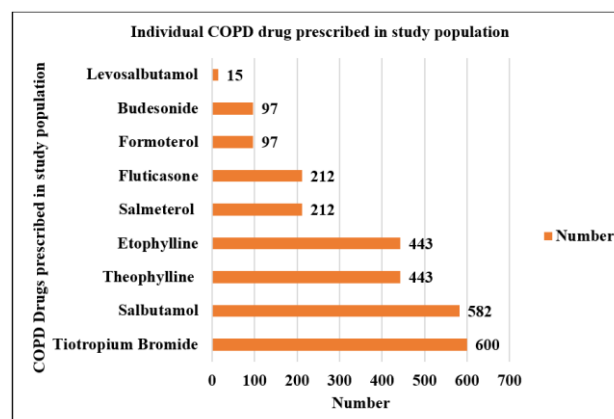
Figure 4: Analysis of the individual drug prescribed for COPD in the study population (n=2701).

In the present study, out of the 2701 drugs prescribed for COPD in the study population, it was noted that Tiotropium Bromide: 600 (22.21%) has been prescribed most commonly in the study population followed by Salbutamol: 582 (21.55%) (Figure 4). Out of 3815, 1680 (44.04%) of them have been prescribed as monotherapy while 2135 (55.96%) of them have been prescribed in the form of combination therapy in the study population (Table 4).

In the present study, out of the 1058 drugs prescribed as fixed dose combination (FDC) in the study population the most commonly prescribed in them was the combination of Theophylline+Etophylline: 443 (41.87%) (Table 5). Regarding DUS parameters, in the present study, out of the 3815 drugs prescribed in the study population, 2382 (62.43%) drugs were included in the National essential list of medicines, 2015. 2636 (69.17%) drugs were included in the WHO essential list of medicines, 2021. Out of the 2701 drugs prescribed exclusively for COPD in the study population, 1376 (50.94%) drugs were included in the National Essential List of Medicines, 2015. 1800 (66.64%) drugs were included in the WHO Essential List of Medicines, 2021. 2662 (69.78%) were prescribed by their generic names. The remaining 1153 (30.22%) drugs were prescribed by their brand names. Out of the 2701 drugs prescribed exclusively for COPD in the study population, 1659 (61.42%) were prescribed by their generic names (Table 6). The remaining 1042 (38.58%) drugs were prescribed by their brand names. 2102 (55.10%) drugs were prescribed from the hospital pharmacy while the remaining 1713 (44.90%) were prescribed from outside. Out of the 2701 drugs prescribed exclusively for COPD in the study population, 1276 (47.24%) drugs were prescribed from the hospital pharmacy while the remaining 1425 (52.76%) was prescribed from outside (Table 6). The present study yielded the prescribed daily dose (PDD)/ daily defined dose (DDD) ratio of the prescribed drugs which showed that majority of the drugs i.e., 19 had PDD/DDD ratio of<1 followed by 6 drugs whose PDD/DDD ratio was>1. 11 drugs had PDD/DDD ratio of 1. The range was 0.12–2. Considering the cost analysis of the present study, the average cost per prescription was 647.23 INR, out of which, the cost borne by the hospital was 356.62 INR (55.10%) and the cost borne by the patient was 290.61 INR (44.90%). Average cost of COPD drugs per prescription was 399.44 INR (Table 7).

Ultimately, at least 4 drugs are prescribed in the patients of COPD population in which anti-muscarinic is the common drug which is prescribed to every single patient of COPD. These drugs are commonly available at all government as well as private pharmacies. Overall burden of the drugs comes around 647.23 INR, out of which, the cost borne by the hospital was 356.62 INR (55.10%) and the cost borne by the patient was 290.61 INR (44.90%) (Table 6). Our study follows most of the GOLD guidelines, still there should be provision of some drugs which are not available in the hospital pharmacy and try to decrease the drug burden to avoid the polypharmacy as well as concomitant drug interaction if the patient has co-morbidities.

Table 4: Drug classes and COPD drugs prescribed in the study population (n=3815).

Drug classes	N (%)
Bronchodilators	2392 (62.70)
Corticosteroids	309 (8.10)
Concomitant	1114 (29.20)
Total	3815 (100)
Drugs prescribed in COPD patients	
Monotherapy	1680 (44.04)
Combination therapy	2135 (55.96)
Total	3815 (100)

Table 5: Drugs prescribed as FDC in the study population (n=1058).

Drugs prescribed as FDC	N (%)
Calcium+Vitamin D	272 (25.71)
Theophylline+Etophylline	443 (41.87)
Salmeterol+Fluticasone	212 (20.04)
Formoterol+Budesonide	97 (9.17)
Amoxycillin+Clavulanic Acid	8 (0.76)
Paracetamol+Diclofenac+Chlorzaxone	19 (1.80)
Furosemide+Spironolactone	3 (0.28)
Clotrimazole+Beclomethasone	4 (0.38)
Total	1058 (100)

Table 6: WHO/INRUD drug indicator in the study population.

(WHO/INRUD drug indicator)	
Average number of drugs per encounter	6.36±2.31
Percentage of drugs prescribed by generic name	69.78%
Percentage of encounter with an antibiotic prescribed	1.80%
Percentage of encounter prescribed an injection	0%
Percentage of drug prescribed from hospital formulary	55.10%
Percentage of drugs prescribed from National List of Essential Medicines, 2015	62.43%
Percentage of drugs prescribed from WHO essential drug list, 2021	69.71%

Table 7: Cost analysis in the study population.

Cost analysis	
Average cost per prescription	647.23 INR
Average cost of COPD drugs per prescription	399.44 INR
Percentage of cost borne by hospital	55.10%
Percentage of cost borne by patient	44.90%

DISCUSSION

COPD represents an important public health challenge that is both preventable and treatable. COPD is a major cause of chronic morbidity and mortality throughout the world; many people suffer from this disease for years and die prematurely from it or its complications. Globally, the COPD burden is projected to increase in coming decades because of continued exposure to COPD risk factors and aging of the population.[15] In the study, the selected age for the inclusion criteria for study population was above 18 years. But the age range of the study was 31 to 85 years. The average age was 62.87 (±10.66) years. Majority of the participants, 243 (40.50%) were in the age group of 61-70 years. The relative distribution in the different age groups was: 18-30 years: 0%, 31-40 years: 1.83%, 41-50 years: 9.33%, 51-60 years: 20.83%, 61-70 years: 40.50%, >71 years: 27.50%. The finding was in accordance with a study conducted by Sharon et al, in which he found that the majority of the patients belonged to age group 61-70 years (44%) followed by>71 years (26%) and 51-60 years (19%).[16]

The findings corroborated with various studies conducted by Singh et al, Unni et al, Sawant et al.[17-19] In all these studies the most common age group associated with COPD was 61-70 years and the second most common age group associated with COPD was >71 years except the studies conducted by Singh et al, in which second most common age group associated with COPD was 51-60 years.[17] Therefore, it can be seen in the present study that the overall prevalence of the population is falling in the age category range of 60-70 years. This can be because 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 elderly patients. In accordance to National Heart, Lung and Blood Institute (NHLBI), typical COPD occurs most often in people above

the age of 40 years who are currently smoking or have smoked for long periods previously, as the progressive nature of the disease reduces the likelihood of young individuals from developing it except in cases of alpha-1 antitrypsin deficiency.[20] In the present study, out of the 600 participants, 508 (84.67%) were males and 92 (15.33%) were females. The approximate male to female ratio is 5.52:1. A study conducted by Kumar et al, had 134 (82%) male and 29 (18%) females amongst the study population.[21] Also, in another study conducted by Veettil et al, of 120 patients having participated in the study, 87.5% were males and 12.5% of them were females.[13] Maqusood et al, conducted a study consisting of total 74 patients. Out of total 60 (81.08%) were males and 14(18.9%) were females.[7]

The maximum number of males 185 (36.42%) were in the age group 61-70 years. The maximum number of females 58 (63.04%) were in the age group 61-70 years. Therefore, the age group of 61-70 years, which has the maximum number of patients (243) had maximum numbers of male and female patients. The present study findings were consistent with the findings of these studies and indicate that the males are more prone to suffer from COPD as compared to females, which get confirmed by demographic results and is largely due to cigarette smoking and other causes can be environmental and occupational exposure to vapor, dust, gas and fumes. But over the years it is seen that the prevalence of the disease is increasing in women dude to increase in cigarette smoking in women in the developed countries and even though cigarette smoking is still less when compared to men, women seem to have higher susceptibility to cigarette smoke thus contributing to the increasing prevalence over the years.[22] Considering the religious distribution, out of the 600 study participants, majority of them 340 (56.67%) belonged to the Hindu religion, followed by the Muslim religion 242 (40.33%). The remaining religion belonged to the Christians 11 (1.83%) and other religions 7 (1.17%). In the present study,

out of the 600 study participants, it was found that Majority of the participants, 242 (40.33%) were having weight in the weight group of 61-70 Kgs. The relative distribution in the different weight groups was - <50 Kgs: 65 (10.83%), 51-60 Kgs, 235 (39.17%), 61-70 Kgs: 242 (40.33%), 71-80 Kgs: 51 (8.50%), >81 Kgs: 7 (1.17%).

The socio-economic distribution of the study population was evaluated in accordance with the modified Kuppuswamy socio-economic status scale. In the present study, out of 600 study participants it was found that the maximum patients belonged to the upper-lower status-399 (66.50%), followed by lower-middle socio-economic status – 134 (22.33%) and then by lower socio-economic status – 30 (5%), upper socio-economic status-20 (3.33%) and last but not the least the upper -middle socio-economic status group-7 (2.83%). The data corresponded to a study conducted by Veettil et al, in which he found that out of 120 patients taken in the study, 50% of them belonged to the upper-lower status group followed by 42.5% in the lower middle status group and 7.5% in the upper middle socio-economic status group.[13]

The maximum number of patients belonging to the upper – lower socio-economic status group can be attributed to the factors like social disadvantages including poverty, discrimination, unemployment etc. Demographic profile of patients who came under this study revealed that most of them were of a low socioeconomic status according to the modified Kuppuswamy scale. This may be because the hospital in which the study was undertaken was a government hospital offering free treatment. Another explanation may be that according to the GOLD guideline, people of low socioeconomic status tend to have increased incidence of COPD.[23,24]

Coming to the division (district-wise) distribution of the study population, out of 600 study participants, majority of them were from the district wise division of Konkan: 510 (85%), followed by from outside the state of Maharashtra 53 (8.83%), Nashik: 12 (2.00%), Nagpur: 9 (1.50%), Aurangabad: 8 (1.33%), Pune: 6 (1.00%), Amravati 2 (0.33%). The maximum patients being from the Konkan division can be attributed to the fact that hospital from the study participants were taken for the study is based in central part of Mumbai which is situated in the wider division (district-wise) of Konkan. Considering the employment status of the study population, it was found in the present study that out of the 600 study participants, 254 (42.33%) patients were employed and 346 (57.67%) were unemployed. In present study, out of the 600 study participants, it was noted that 260 (43.33%) patients were smokers, 129 (21.50%) patients were ex-smokers and 211 (35.17%) patients were non-smokers The data corresponds to study conducted by Kumar et al, in which among 163 patients, 64 (39.63%) were smokers, 36 (21.95%) were ex-smokers and 63 (38.42%) were non-smokers.[21] In another study conducted by Sharon et al, in which out of 100 study participants, 33% were smokers, 27% were ex-smokers, 40% were non-smokers.[16] 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.

In present study, out of the 600 study participants, it was found that 347 (57.83%) patients are not having any Co-morbidity and 136 (22.67%) patients are having Hypertension which is the most common co-morbidity in patients with COPD followed by osteoarthritis 33 (5.50%), ischemic heart disease 32 (5.33%), diabetes 20 (3.33%), tinea corporis 9 (1.50%), cerebrovascular accident 7 (1.17%), epilepsy 6 (1%), seborrheic dermatitis 4 (0.67%), chronic kidney disease 3 (0.50%), hypothyroidism 3 (0.50%). The data corresponded to study conducted by Sharon et al, in which out of 100 patients the most commonly found co-morbid conditions were Hypertension (31.57%).[16]

Study conducted by Kumar et al, in which out of 163 patients, 117 (71.77%) were not having any other comorbid condition the most common comorbidity was hypertension 32(19.63%).[21] In another study conducted by Vyas et al, in which out of 90 patients, 44.4% of patients were with co-morbid conditions, in which top of the list was Hypertension.[25] Hypertension is frequently seen in COPD patients because of loss of alveolar remodelling 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. A total of 3815 drugs were prescribed in our study population considering FDC as a separate drug, out of which 2392 (62.70%) were bronchodilators, 309 (8.10%) were corticosteroids, 1114 (29.20%) were concomitant medications.

The minimum drugs per prescription were 2 in 47 such patients and the maximum drugs per prescription encountered was 12 in 11 such patients. The average number of drugs prescribed per prescription in the study population was 6.36±2.31 whereas the average number of drugs prescribed for COPD in the study population was 4.50±1.42. The data corresponded to studies conducted by Sawant MP., et al, in which the average number of drugs prescribed per prescription was 7.[19] Thus, it can be inferred in the present study and other corresponding studies that combination of various drugs is prescribed for the management of COPD and various associated illness for better prognosis of the patients. Unfortunately, there are many negative consequences associated with polypharmacy. It is associated with increased health care costs and an increased risk of adverse drug events (ADEs), drug interactions, medical non-adherence and reduced functional capacity. In our study, out of all classes of drugs, the class of drugs prescribed exclusively for the management of COPD were 2, making a total number of drugs to 2701 (70.80%) out of total 3815 drugs given in

600 prescriptions. The remaining drugs prescribed were used as treatment for comorbidities and the other drugs were categorized as Concomitant medications (29.20%). Among all the classes of drugs prescribed exclusively for the treatment of COPD, the bronchodilators group were the most commonly prescribed class of drugs, with 2392 (88.56%). This observation was in concordance with the study conducted by Singh et al, in which bronchodilators were most commonly prescribed class of drugs in COPD. The other classes of drugs prescribed were Corticosteroids with 309 (11.44%).[17] It was also found in another study conducted by Kumar et al, that bronchodilators were most commonly prescribed class of drugs in COPD.[21] 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.

Among the Bronchodilators group, the β2–Sympathomimetic classes of Bronchodilator was the more common one to be prescribed in the study population with 906 (37.88%). This observation was in concordance with the study conducted by Veettil et al, Kumar et al and Maqusood et al, in which β2–Sympathomimetic were most commonly prescribed class of Bronchodilator prescribed in COPD.[7,13,21] The other classes of drugs prescribed were belonged to the group of methylxanthines with 886 (37.04%) and the anticholinergic group of bronchodilators with 600 (25.08%).

β-agonists (bronchodilators) are the main stay in the therapy as outlined by GOLD guidelines. Our finding is in concordance with GOLD guidelines, which recommends inhaled short acting β2 agonist with or without short acting anticholinergic agent as the preferred bronchodilator for treatment of exacerbations. These drugs are the first choice in therapy as they rapidly improve respiratory symptoms during an exacerbation.[26] In the current study, four different types of β2–sympathomimetic were prescribed in the study population. Among the four, Salbutamol was prescribed more as compared to other β2–sympathomimetic in 582 (64.24%) of the total prescriptions. The data corresponded to a study conducted by Veettil et al, in which he found that the salbutamol was among the most commonly prescribed (74%) in the study population among the β-agonists.[13] Similar study conducted by Kumar et al, in which Salbutamol (65.89%) was the mostly prescribed drug.[21] Salbutamol is the first choice in therapy among β-agonists as they rapidly improve respiratory symptoms during an exacerbation.

Out of the 2701 drugs prescribed for COPD in the study population, it is noted that Tiotropium Bromide: 600 (22.21%) has been prescribed most commonly in the study population followed by Salbutamol: 582 (21.55%), Theophylline: 443 (16.40%), Etophylline: 443 (16.40%), Salmeterol: 212 (7.85%), Fluticasone: 212 (7.85%), Formoterol: 97 (3.59%), Budesonide: 97 (3.59%) and Levosalbutamol: 15 (0.56%). The data corresponded to a study which was done in Karnataka by Uday Kumar P et al, it was seen that out of 80 prescriptions analysed 73 of them had tiotropium prescribed in them i.e., 96%.[27] In another study done in Kerala by Unni et al, in which it was seen that out of the prescriptions of 237 COPD patients the most commonly prescribed drugs were ipratropium (91.6%).[18] Anti-cholinergic are prescribed in COPD to maintain the bronchodilation. Reports favor the early administration of anticholinergics as it has shown to reduce exacerbation rate and improve the time taken for first exacerbation supporting its recommendation in guidelines.[28]

Among the corticosteroids, fluticasone (7.85%) and budesonide (3.59%) are commonly prescribed to the study population in the present study. The data corresponded to a study which was done by Unni et al, in which it was seen that fluticasone & budesonide were the most commonly prescribed corticosteroids.[18] Corticosteroids improve lung function and reduce the frequency of exacerbations which in turn shortens the recovery time. It can therefore be inferred from the present study and other corresponding studies that β2 agonist with anticholinergic agent as the preferred bronchodilator for treatment of exacerbations. It is noted in the present study that out of the 3815 drugs prescribed for COPD in the study population, 1680 (44.04%) of them have been prescribed as monotherapy while 2135 (55.96%) of them have been prescribed in the form of combination therapy in the study population. The data contrast to a certain study conducted by Sharon et al, in which he found that 45% of the patients were receiving combination therapy while 55% of them were prescribed monotherapy.[16]

Drug combinations were used to decrease COPD symptoms, increase drug effectiveness and decrease the medication dose. Regarding the concomitant medications, Out of the 1114 concomitant medications prescribed in the study population, the most commonly prescribed drug is Vitamins and Minerals: 661 (59.34%), followed by NSAIDs: 103 (9.25%), ARB: 79 (7.09%), PPI: 58 (5.21%), CCB: 57 (5.12%), Antifungal: 31 (2.78%), Biguanide: 20 (1.80%), Antibiotics: 20 (1.80%) Mephenesin Congeners: 19 (1.71%), Statins: 13 (1.17%), H1 Antihistaminic: 10 (0.90%), Loop Diuretics: 7 (0.63%), Antiepileptics: 6 (0.54%), Emollents: 4 (0.36%), β-Blockers: 4 (0.36%), ACE Inhibitors: 4 (0.36%), Corticosteroids: 4 (0.36%), H2 Antihistamines: 4 (0.36%), Oxidizing Agent: 4 (0.36%), Aldosterone Antagonist: 3 (0.27%), Thyroid Hormones: 3 (0.27%). The data was in contrast to the study conducted by Kumar S., et al, in which 682 (31.35%) concomitant drugs were prescribed. In which the other drugs commonly co-prescribed are H2 antagonist 106(15.54%) followed by paracetamol 105(15.4%) followed by antihypertensive drugs 85(12.46%).[21] In the present study, out of the 1058 drugs prescribed as fixed dose combination (FDC) in the study population the most commonly prescribed in them was the combination of Theophylline+Etophylline: 443 (41.87%). Data was compliant with another study conducted by Kumar et al, in which it was found that Theophylline+Etophylline (39.26%) were most commonly

prescribed drugs in combination used in the management of COPD.[21] In the present study, out of the 3815 drugs prescribed in the study population, 2382 (62.43%) drugs were included in the National essential list of medicines, 2015. 2636 (69.17%) drugs were included in the WHO essential list of medicines, 2021. Out of the 2701 drugs prescribed exclusively for COPD in the study population, 1376 (50.94%) drugs were included in the national essential list of medicines, 2015. 1800 (66.64%) drugs were included in the WHO essential list of medicines, 2021.

Essential list of medicines are those that satisfy the priority health care need of the majority of the population and are selected with due regard to disease prevalence, evidence on efficacy and safety and comparative cost-effectiveness. They are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and at a price, the individual and the community can afford.[29] The primary purpose of the NLEM is to promote rational use of medicines considering the three important aspects i.e., cost, safety and efficacy. There were 2662 (69.78%) drugs which were prescribed by their generic names. The remaining 1153 (30.22%) drugs were prescribed by their brand names. 2102 (55.10%) drugs were prescribed from the hospital pharmacy while the remaining 1713 (44.90%) was prescribed from outside.

The reason for this may be a smaller number of generic prescriptions or unavailability of some of the drugs in the hospital pharmacy or absence of some of the drugs in the rate contract (RC) list of the state government. The drugs that were available and dispensed from the hospital pharmacy included generic drugs as well as few of the branded drugs that were dispensed from the generic drug stock of the hospital pharmacy at the level of the pharmacist. This in a way reduced a little expenditure on drugs that the patient had to bear for purchasing the drugs from outside medical stores. Prescribing generic drugs for long-term treatment thus, would significantly reduce the economic burden on the patient.

The following data contrast to a study conducted by Kumar et al, in which he found that the 90.27% of the drugs were prescribed from the WHO essential list of medicines 2017 and only 1.42% of the drugs were prescribed by their generic name.[21] Thus, the present study showed a higher rate of prescribing of drugs by their generic name. This may indicate less inclination of the prescribing doctors to prescribe branded drugs and thus avoiding the promotion of any specific brands. This also helps to prevent the causation of confusion and prescribing errors among the pharmacists dispensing these drugs. Generic drug prescriptions can be beneficial provided adequate quality control can be maintained and decent quality of generic drugs being made available in the pharmacy shops. Increasing generic prescribing would rationalize the use, reduce the cost of drugs and make the treatment more cost-effective and economical. The present study yielded the

PDD/DDD ratio of the prescribed drugs which showed that majority of the drugs i.e., 19 had PDD/DDD ratio of <1 followed by 6 drugs whose PDD/DDD ratio was >1. 11 drugs had PDD/DDD ratio of 1. The range was 0.12 – 2. A study conducted by Sawant et al, yielded the PDD/DDD ratio in the range of 0.25–4.15.[19] It is important to note that the PDD can vary according to both the illness treated and national therapeutic practices.

The PDDs also vary substantially between different countries, for example, PDDs are often lower in Asians than in Caucasian populations. Because of this, it may seem as if there is an underutilization of a particular drug as per the PDD/ DDD ratio. Also, the DDDs obtained from the WHO ATC/ DDD website are based on international data and are applicable for the management of conditions of moderate intensity. The WHO encourages countries to have their own DDD list based on indigenous data. The ATC classification system divides drugs into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.[30] Considering the cost analysis of the present study, the average cost per prescription was 647.23 INR, out of which, the cost borne by the hospital was 356.62 INR (55.10%) and the cost borne by the patient was 290.61 INR (44.90%). Average cost of COPD drugs per prescription was 399.44 INR.

The cost was calculated, for all the drugs that were encountered in the prescription. The difference between the cost borne by the patient and that by the hospital was not that significant which might be attributed to the fact that despite having a smaller number of generic prescriptions, the patient received generic drugs as well as few of the branded drugs from the stock which was available from the hospital pharmacy store. These drugs were provided free of cost to the patients that reduced the overall economic burden on the patient. This being a government hospital, the majority of the patients that come here are of low social-economic background, thus receiving medicine free of cost helps improve the compliance of the treatment and encourages them for regular follow up to refill their prescriptions.

The present study observed polypharmacy and prescription of more drugs with branded names so doctors should be encouraged to prescribe more drugs with the generic name. Also, the WHO indicators were followed diligently in the terms of adequate drug prescribing patterns. However, it has to be kept in mind that the drugs for COPD are prescribed for long durations of time for which their safety comprises a significant amount of thought behind prescribing the right drug for the patient. Also, that drug needs to be less in cost so as to reduce to economic burden and needs to be readily available in the hospital pharmacy as and when it is required. In order to accommodate all these significant factors, studies need to be done in the future followed by designing of national guidelines that needs to be adopted so that the right drug can be given to the right patient for the right appropriate disease condition.

CONCLUSION

COPD is a very important health problem in our country and significant number of deaths happened due to COPD worldwide. Also, it has a significant impact on the individual finances and economy. Multiple drugs are prescribed for the management of COPD patients at one point of time. Sympathomimetics (salbutamol), anti-cholinergic (tiotropium bromide), methyl xanthine (theophylline+etophylline) and ICS (Fluticasone) are the important classes of drugs prescribe for COPD patients. As a multi-factorial etiology and clinical features, polypharmacy is seen in all the prescriptions encountered in our study population. Cost wise there is significant burden on the patients as well as hospitals. And as it is a long standing therefore economy plays a vital role in the whole management of COPD. In our study, drugs prescribed and drug prescription indicators are in accordance with the various other studies conducted and as per the GOLD Guidelines given for the management of COPD.

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