ORIGINAL ARTICLE

INTERNATIONAL JOURNAL OF CLINICAL PHARMACOKINETICS AND MEDICAL SCIENCES
Published by Pharma Springs Publication Journal Home Page: https://pharmasprings.com/ijcpms/

Assessment of Effectiveness of Clinical Pharmacist Intervention in COPD Patients

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Article History:

Received on: 01 Nov 2021
Revised on: 14 Nov 2021
Accepted on: 15 Nov 2021

Keywords:

Chronic Obstructive Pulmonary Disease, Pharmaceutical Care, Interventions, Adverse Drug Reactions, Drug-Drug Interactions, Medication Adherence

ABSTRACT

Chronic Obstructive Pulmonary Disease (COPD) is characterized as chronic airflow limitation that is due to airway or alveolar abnormalities generally caused by significant exposure to noxious particles or gases. COPD is one extreme cause of morbidity and mortality. It is currently considered as 11^{th} leading cause of disability worldwide. Smoking is one main cause where at least four among five people who developed disease are smokers. Pharmaceutical care helps in improving the recovery of COPD patient in terms of health status and quality of life among them. Pharmacist intervention improved quality of life of patients with COPD. The aim is to assess the impact of clinical pharmacist intervention in COPD patients. The primary objective is to assess the effectiveness of clinical pharmacist intervention in COPD patients by providing pharmaceutical care and the secondary objective is to identify ADR's and Drug-Drug Interactions. It is a Prospective hospital based interventional study. A total of 150 patients were enrolled into the study from Inpatient wards, they were randomly divided into intervention and non-intervention groups with 75 patients each. The study was carried out for a period of 6 months during which pharmaceutical care was provided to intervention group, patient consent form was taken from each patient.Pharmaceutical care was provided to the intervention group by providing patient counseling and by performing active pharmacist interventions that had increased medication adherence level and reduction in occurrence of adverse drug reactions, interactions in patients. We conclude from our study that the presence of a clinical pharmacist and with the interventions in a hospital setup will definitely improve the health status and quality of life of a COPD patient.

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eISSN: 2583-0953

DOI: https://doi.org/10.26452/ijcpms.v1i4.282

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INTRODUCTION

Persistent obstructive pulmonary disease (COPD) is defined as a chronic restriction of airflow caused by anomalies in the airway or alveoli, which are usually induced by considerable exposure to noxious particles or gases. COPD relates to Emphysema and Chronic Bronchitis, where Emphysema is pathologically defined as alveolar wall breakdown and air space expansion, and Chronic Bronchitis is inflammation and fibrosis of the small airways that lasts for at least 3 months for at least 2 years [1, 2].

COPD is one extreme cause of morbidity and mortality. It is currently considered as 11^{th} leading cause of disability worldwide. The prevalence of COPD

Table 1: Distribution of Patients Based on Age

Age (Years)	No. of Patients (%)	
	Intervention Group	Non-Intervention Group
30-39	2 (2.6)	3 (4)
40-49	4 (5.3)	5 (6.6)
50-59	14 (18)	13 (17.3)
60-69	36 (48)	25 (33.3)
70-79	15 (20)	25 (33.3)
80-89	4 (5.3)	4 (5.3)
Total	75 (100)	75 (100)

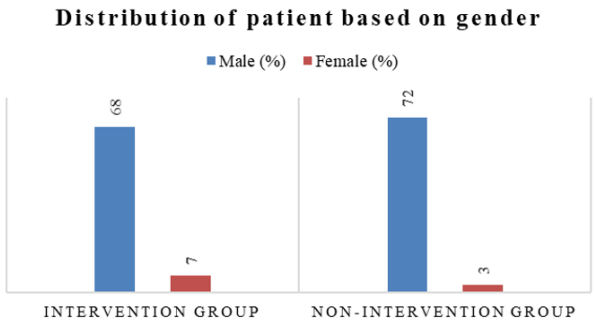

Figure 1: Distribution of Patient Based on Gender

cases are about 281 million in 2016 and the estimated deaths were 3.17 million in 2015 in the worldwide [3]. In the world, there were 5% deaths annually. It is the second leading cause of death in India by 2016 [4]. Prevalence of COPD is high in men when compared to women and most common in age of 60 years and above population. Smoking is one main cause where at least four among five people who developed disease are smokers. This damage by inflammation of airway lining is permanent and cannot be reversed. Environmental Pollution such as indoor air pollution and fumes, dust are some other common risk factors of COPD [5].

COPD causes airway obstruction that typically progresses due to pathologic alterations in the lung that impact the proximal airways, lung parenchyma, and pulmonary vasculature. Chronic inflammation causes repeated damage and changes in tissue structure [6]. Any patient with dyspnea, persistent cough, or sputum production, as well as a history of exposure to COPD risk factors, should be examined for the condition [3]. Spirometry testing, arterial blood gas measurement, Chest X-ray are the best tools to diagnose COPD. The severity of COPD can be assessed by the stages from GOLD guidelines [2].

The major aims of COPD care are to avoid or control symptoms, minimize the frequency and severity of exacerbations, and enhance overall health and activity tolerance [7]. According to Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) Guidelines, Bronchodilators, Long and Short acting Beta 2-agonists, Long and Short acting Anti-Cholinergic/Muscarinic drugs, methylxanthines, Systemic or inhaled corticosteroids and Antibiotics are the most commonly used medications in the treatment of COPD [2]. The role of nutrition has a great association with the COPD. Malnutrition and weight loss can diminish respiratory muscle strength and endurance, presumably by lowering both respiratory muscle mass and residual muscular fibre strength [8, 9].

Pharmaceutical care helps in improving the recovery of COPD patient in terms of health status and quality of life among them. Pharmacist intervention improved quality of life of patients with COPD [10, 11]. Present study is to assess effectiveness of clinical pharmacist intervention in COPD patients. The goal of our research is to show that pharmacists should be more involved in the management of COPD patients.

Aim and Objectives

The primary objectives of the study include:

1. To assess the impact of clinical pharmacist intervention in COPD patients.
2. To assess the effectiveness of clinical pharmacist intervention in COPD patients by providing pharmaceutical care.
3. To provide patient counseling to the patients.

The secondary objectives of the study include:

1. To observe the adverse drug reactions.
2. To monitor the drug interactions.

Table 2: Demographic Details

Parameter	No. of Patients (%)
Area of Residence	
Urban	47 (31.3)
Rural	103 (68.7)
Body Mass Index (BMI)	
Underweight (<18.5)	25 (16.6)
Healthy weight (18.5-24.9)	80 (53.3)
Over weight (25-29.9)	39 (26)
Obese (>30)	6 (4)
Co-morbidities	
Diabetes Mellitus	13 (8.6)
IHD	9 (6)
Cor Pulmonale	10 (6.6)
Past PTB	4 (2.6)
Hypothyroidism	2 (1.3)
Hypertension	6 (4)
More than 1 co-morbidity	31 (20.9)
No co-morbidities	75 (50)
Social Habits	
Smoking	116 (77.3)
Chewing Gutka	1 (0.8)
Smoking and Alcohol	9 (6)
No Social Habits	24 (16)
Exposure to Risk Factors	
Smoking	124 (82.6)
Smoking and biomass fumes	1 (0.74)
Biomass fumes	10 (6.6)
No exposure	15 (10)
Diagnosis	
Newly Diagnosed with COPD	68 (45.3)
Exacerbations of COPD	82 (54.7)
Management	
Antibiotics	72 (96%)
Bronchodilators	75 (100%)
Diuretics	35 (46.6%)
Mucolytic	23 (30.6%)
Analgesics and Anti-pyretic	20 (26.6%)
Antacids	42 (56%)
Oxygen Inhalation	12 (16%)

Table 3: Distribution of ADR's Observed in the Patients

Drug Name	ADR	No. of Patients	
		Intervention Group	Non-Intervention Group
Neb. Duolin	Tachycardia	3	8
Neb. Duolin	Generalized itch	-	1
Pantocid	Abdominal pain	1	2
Furosemide	Hypokalemia	2	5
Neb. Duolin	Constipation	-	3
Neb. Budecort	Oral Candidiasis	3	8
T. Nifedipine	Pedal edema	1	3
T. Clarithromycin	Abdominal pain	-	2
Neb. Budecort	Headache	-	1
T. Ranitidine	Itching and rash	-	3
Total		9	36

METHODOLOGY

Study Site

This study was conducted at the SDS TRC Rajiv Gandhi Institute of Chest Diseases, Bengaluru.

Study Design

A prospective hospital based interventional study.

Sample Size

A total of 150 patients were enrolled into the study from Inpatient wards of SDSTRC Rajiv Gandhi Institute for Chest Diseases, 150 patients were randomly divided into intervention and non-intervention groups with 75 patients each.

Study Duration

The study is conducted over a period of 6 months from November 2017 to April 2018.

Study Criteria

The study is carried out by considering the following inclusion and exclusion criteria after taking consent from the people involved in the study.

Inclusion Criteria

1. All patients above the age of 18 years.
2. In-patients who are confirmed with COPD based on GOLD criteria.

Exclusion Criteria

1. Patients with any other respiratory diseases.
2. Pregnant and breast feeding women.
3. Patients who refuse to participate in the research.

Source of Data

1. Patients case sheets.
2. Interview with patients/attenders.
3. Interview with consultants.

Study Procedure

On a daily basis, I went to ward rounds and gathered cases that met the inclusion criteria. The patients were placed into two groups at random: intervention and control. The intervention group received all the pharmaceutical care such as patient counseling, ADR and DI monitoring. The data collected were pooled and analyzed.

Statistical Analysis

All the data have been statistically analyzed. Continuous variables were reported using mean +/- SD (standard deviation) for the normally distributed variables otherwise median and quartiles were used. Categorical variables were reported using number and percentages. Continuous variables which are normally distributed were compared between intervention and non-intervention group using Independent t-test. Otherwise, For comparison, the Mann Whitney U test was employed. The Chi-square test or Fisher's Exact test were used to compare the distribution of categorical variables between the intervention and non-intervention groups. SPSS version 24 was used for all of the analysis. At the 5% level, all of the analyses were deemed statistically significant (p-value <0.05).

Ethical Approval

The Institutional Ethics Committee of Al-Ameen College of Pharmacy in Bangalore gave its approval.

Table 4: Drug Interactions in Both the Groups

Drug Name	Interacting Drug	Pharmacological Outcome	No. of Patients	
			Intervention Group	Non-Intervention Group
Salbutamol	Theophylline	Increased BP, HR and Hypokalemia	42	43
Salbutamol	Furosemide	Hypokalemia	26	23
Salbutamol	Budesonide	Hypokalemia	64	60
Salbutamol	Hydrocortisone	Hypokalemia	52	55
Salbutamol	Azithromycin	Arrhythmias	15	25
Theophylline	Hydrocortisone	Hypokalemia, Hyperglycemia	38	50
Theophylline	Budesonide	Hypokalemia	42	22
Theophylline	Azithromycin	Decrease in the activity of theophylline	15	25
Theophylline	Ranitidine	Decrease in the effect of theophylline	4	15
Theophylline	Ciprofloxacin	Theophylline toxicity, Cardiac symptoms, seizures	-	3
Ceftriaxone	Furosemide	Nephrotoxicity	18	28
Diclofenac	Hydrocortisone	Hypokalemia	-	10
Ceftazidime	Furosemide	Nephrotoxicity	-	5
Furosemide	Budesonide	Hypokalemia	-	28
Ranitidine	Budesonide	Hyperacidity	-	15
Torsemide	Cefoperazone	Nephrotoxicity	-	4
Ciprofloxacin	Hydrocortisone	Tendonitis	-	3
Furosemide	Hydrocortisone	Hypokalemia	26	-
Furosemide	Sildenafil	Hypotension	2	-
Clarithromycin	Budesonide	Increased absorption of Budesonide	22	-
Clarithromycin	Hydrocortisone	Increased Hydrocortisone toxicity	20	-
Clarithromycin	Sildenafil	Nausea, vomiting, shortness of breath	2	-
Diclofenac	Budesonide	GI toxicity	5	-
Torsemide	Ceftriaxone	Nephrotoxicity, nausea, vomiting	3	-
Torsemide	Sildenafil	Dizziness	4	-
Torsemide	Salbutamol	Hypokalemia	9	-
Cefotaxime	Amikacin	Nephrotoxicity	1	-

Table 5: Distribution of Patients Based on Medication Adherence According to MMAS-8 Score

Total scores	MMAS-8	At the time of Admission No. of Patients (%)		At the time of Discharge No. of Patients (%)	
		Intervention	Non-Intervention	Intervention	Non-Intervention
0		9 (12)	4 (5.3)	11 (14.6)	4 (5.3)
1		14 (18.6)	22 (29.6)	18 (24.3)	23 (30.6)
2		15 (20.3)	11 (14.6)	16 (21.3)	11 (14.6)
3		5 (6.6)	8 (10.6)	6 (8)	9 (12)
4		7 (9.3)	7 (9.3)	7 (9.3)	8 (10.6)
5		8 (10.6)	9 (12)	8 (10.6)	8 (10.6)
6		6 (8)	5 (6.6)	4 (5.3)	4 (5.3)
7		10 (13.3)	6 (8)	5 (6.6)	6 (8.4)
8		1 (1.3)	3 (4)	0 (0)	2 (2.6)
Total		75 (100)	75 (100)	75 (100)	75 (100)

RESULTS AND DISCUSSION

The study was carried out for a period of 6 months during which pharmaceutical care was provided to intervention group, patient consent form was taken from each patient. Distribution of patient based on Gender was represented in Figure 1. Table 1 show that the majority of the patients in the research were between the ages of 60 and 69 and 70 and 79, indicating that the frequency of COPD rises with age. This finding was found to be comparable to that of Maher R Khouda et al. study [12].

Because smoking and biomass are the most prevalent etiological factors for COPD, the location of residence is significant, and the majority of the individuals were from rural areas. It's also likely that this conclusion is based on the fact that the research centre was a district hospital. Though BMI has no direct influence on COPD patients, it was taken into account because it is one of the predisposing variables for the disease. Half of the patients in the study group were found to be healthy.

When it comes to prescription medications, co-morbidities are quite important. The majority of patients did not have any co-morbidities, although a small number of patients had, such as diabetes, high blood pressure, and so on, as shown in Table 2. When it comes to the second crucial element, social behaviours, it was discovered that the majority of them smoke, and it is well known that the prevalence of COPD is directly linked to smoking.

The severity of illness relies on the risk factors that are present. In light of this, it was discovered that the vast majority of the patients had been exposed to smoking. The biomass fumes had been inhaled by all of the female patients. Surprisingly, several of the patients had never been exposed to risk factors, yet a handful had a family history of COPD. The majority of the patients were hospitalised due to COPD exacerbations.

In the prevention and development of disease, proper diagnosis and sensible use of treatment are critical. Bronchodilators and antibiotics were used to treat all of the patients, with analgesics, diuretics, mucolytics, and oxygen inhalation being recommended in a few cases.

Since all drugs have the potential to develop adverse drug reactions, monitoring ADR is an important duty of Clinical Pharmacist and it was observed that maximum number of ADR's were seen in the non-intervention group than the intervention group. The most common ADR observed were tachycardia caused by duolin, oral candidiasis caused by budecort, hypokalemia caused by furosemide as shown in the Table 3. According to Naranjo Causality Assessment scale, maximum number of ADRs were found to be probable.

Drug-Drug Interactions can lead to reduced efficacy of the treatment or cause untoward effect to patients by either synergism or antagonism effect. Out of 150 prescriptions, all had one or other interaction but none of them reached the patients in either the groups. The most common DDI observed was with salbutamol and budesonide, salbutamol and hydrocortisone, theophylline and hydrocortisone as shown in Table 4.

Medication adherence was checked for all the study subjects at the time of admission and at the time of discharge by using MMAS 8 score. It was clearly observed that the intervention group had high adherence at time of discharge than other group as shown in Table 5. These results were discovered to be identical in a research conducted by Faheemudin

et al. [13].

CONCLUSION

The bulk of the patients in our research were male. A common etiological component was found to be smoking. Cough, wheezing, dyspnea, and fever were the most prevalent clinical manifestations. The majority of the patients were COPD exacerbations rather than new COPD episodes. The most commonly used drugs were bronchodilators as inhalation, systemic and oral dosage forms, inhaled and systemic steroids, antibiotics in most of the patients and in some cases, oxygen inhalation was used to maintain optimum oxygen saturation levels. Pharmaceutical care was provided to the intervention group by providing patient counseling and by performing active pharmacist interventions that had increased medication adherence level and reduction in occurrence of adverse drug reactions, interactions in patients. The pharmaceutical care group stayed for lesser period of time when compared to other as their recovery rate was fast and it was observed that the choice of the drugs during discharge were minimal for them which clearly indicates that the pharmaceutical care provided by the Clinical pharmacist that have improved the health status of the COPD patients. We conclude from our study that the presence of a clinical pharmacist and with the interventions in a hospital setup will definitely improve the health status and quality of life of a COPD patient.

Funding Support

The authors declare that they have no funding support for this study.

Conflict of Interest

The authors declare that there is no conflict of interest.

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Cite this article: Mohammed Tanzeel, Ghazala Anjum K, Pulimi Divya Priyanka, Sayimpu Sai Babu, Vithya T. **Assessment of Effectiveness of Clinical Pharmacist Intervention in COPD Patients**. Int. J. of Clin. Pharm. Med. Sci. 2021; 1(4): 184-191.