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Impact of Pharmacist Integrated Care on Quality Of Life of Copd Patients – A Prospective Study

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ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is characterized by airflow limitation that is not fully reversible and is one the most prevalent chronic respiratory diseases which requires continuous medication therapy. The clinical pharmacist can play an effective role through providing patient counselling to improve quality of life and medication adherence. **Aim and objective**: The aim of the study is to evaluate the impact of pharmacist integrated care on quality of life of COPD patients. **Methods:** A prospective study (on a intervention and control group) was conducted in Pulmonology department in valluvanad hospital for period of one year. Quality of life assessed by St George's Respiratory Questionnaire and medication adherence by MMAS-8. **Results:** A total of 150 COPD patients were enrolled .The St George's Respiratory Questionnaire scores of symptom (55.97 vs. 53.90, P-value<0.05), activity (76.69 v s.75.76 P-value<0.05) and impact (59.10 vs. 56.62, P-value<0.05) of intervention group showed a signifi-+cantly greater improvement as compared with the baseline. The MMAS-8 score was found to be improved significantly in the intervention group (5.52±1.71 vs.7.24 ±1.13, p<0.05). **Conclusion:** The pharmacist integrated care on intervention group showed improvement in quality of life and medication adherence. Therefore clinical pharmacists must be considered as an integral element of healthcare system.**KEYWORDS:** COPD, St George's respiratory questionnaire, Morisky medication adherence scale -8.

I. INTRODUCTION

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Chronic obstructive pulmonary disease (COPD) is characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases. The most common conditions comprising COPD are chronic bronchitis and emphysema.

Chronic bronchitis is associated with chronic or recurrent excess mucus secretion into the bronchial tree with cough that occurs on most days for at least 3 months of the year for at least 2 consecutive years when other causes of cough have been excluded. Emphysema is defined as abnormal, permanent enlargement of the airspaces distal to the terminal bronchioles, accompanied by destruction of their walls, but without obvious fibrosis. [1]

Quality of life is defined by World Health Organization (WHO) as a broad and complex concept of individual about their physical health, mental health and social relationship. QOL refers to the coverage of a broad range of content, including physical, functional, emotional, and social well-being. It is assumed that by aggregating (i.e., combining) measures of these various aspects of functioning; one can approximate a single index of QOL. ". Chronic illness of COPD is frequent in general population. COPD diseases are characterized by a narrowing of bronchi associated with chronic inflammation. [2]

Medication adherence can be defined as an extent to which patient behavior coincides with health-related advice and ability of patient to take medications as prescribed. Adherence to the medication has reported to be low among patients with COPD. The major reasons for medication non-compliance were felt better and stopped, high cost of medications, forgetfulness, fear of side

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effects, non-beneficial treatment. Poor compliance with prescribed therapy leads to increased morbidity and mortality [3]

EPIDEMIOLOGY

In India, the burden of all non-communicable diseases has increased since 1990. As on 2016, three out of five leading causes of mortalities constitute non-communicable diseases whereas COPD is the second biggest cause of death in India today. Different studies have revealed varying range of prevalence of COPD in different states. The prevalence ranged between 2 to 22% among the men and 1.2 to 19% among women in different population-based studies across India. It became fourth leading cause of years of life lost in Empowered Action Group (EAG) States including Bihar, Jharkhand, Madhya Pradesh, Chhattisgarh, Odisha, Rajasthan, Uttar Pradesh and Uttarakhand. Also, COPD ranked seventh among the North-East States including Assam, Mizoram, Arunachal Pradesh, Meghalaya, Nagaland, Tripura, Sikkim and Manipur. Among the remaining states of India, COPD ranked fourth among all causes of years of life lost in this varying range of disease burden, the highest rate of death from COPD was nine times the lowest rate among all the states.

ETIOLOGY

Smoking: cigarette smoking is the most common risk factor and accounts for 85% to 90% of cases of COPD. Components of tobacco smoke activate inflammatory cells, which produce and release the inflammatory mediator's characteristics of COPD. [1]

Fumes and dust: Exposure to certain types of dust and chemicals at work may damage the lungs and increase the risk of COPD.

- Substances that have been linked to COPD include:
- Cadmium dust and fumes
- Grain and flour dust
- Silica dust
- Welding fumes
- Isocyanates
- Coal dust

Alpha-1-antitrypsin deficiency: In about 1% of people with COPD, the disease results from a genetic disorder that causes low levels of a protein called alpha-1-antitrypsin (AAt). AAt is made in the liver and secreted into the bloodstream to help protect the lungs. Alpha-1-antitrypsin deficiency can cause liver disease, lung disease or both.[5]

PATHOPHYSIOLOGY

The most common etiology is exposure to environmental tobacco smoke, but other chronic inhalational exposures can also lead to COPD. Inhalation of noxious particles and gases stimulates the activation of neutrophils, macrophages, and CD8+ lymphocytes, which release a variety of chemical mediators, including tumor necrosis factor-α, interleukin-8, and leukotriene B4. These inflammatory cells and mediators lead to widespread destructive changes in the airways, pulmonary vasculature, and lung parenchyma.

- Other pathophysiologic processes may include oxidative stress and an imbalance between aggressive and protective defense systems in the lungs (proteases and antiproteases). Increased oxidants generated by cigarette smoke react with and damage various proteins and lipids, leading to cell and tissue damage. Oxidants also promote inflammation directly and exacerbate the protease-antiproteases imbalance by inhibiting antiproteases activity.[1]

- The protective antiproteases α1-antitrypsin (AAT) inhibits several protease enzymes, including neutrophil elastase. In the presence of unopposed AAT activity, elastase attacks elastin, which is a major component of alveolar walls. A hereditary deficiency of AAT results in an increased risk for premature development of emphysema. In the inherited disease, there is an absolute deficiency of AAT. In emphysema resulting from cigarette smoking, the imbalance is associated with increased protease activity or reduced activity of antiproteases. Activated inflammatory cells release several other proteases, including cathepsins and metalloproteinases. In addition, oxidative stress reduces antiproteases (or protective) activity.

- An inflammatory exudate is often present in the airways that lead to an increased number and size of goblet cells and mucus glands. Mucus secretion increases, and ciliary motility is impaired. There is thickening of the smooth muscle and connective tissue in the airways. Chronic inflammation leads to scarring and fibrosis. Diffuse airway narrowing occurs and is more prominent in small peripheral airways.

- Parenchymal changes affect the gas-exchanging units of the lungs (alveoli and

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pulmonary capillaries). Smoking-related disease most commonly results in centrilobular emphysema that primarily affects respiratory bronchioles. Pan lobular emphysema is seen in AAT deficiency and extends to the alveolar ducts and sacs.

- Vascular changes include thickening of pulmonary vessels that may lead to endothelial dysfunction of the pulmonary arteries. Later, structural changes increase pulmonary pressures, especially during exercise. In severe COPD, secondary pulmonary hypertension leads to right-sided heart failure (cor pulmonale).[1]

II. SIGNS AND SYMPTOMS

The diagnosis of COPD is made based on the patient's symptoms including cough, sputum production and dyspnea and a history of exposure to risk factors such as tobacco smoke and occupational exposure.

The physical examination is normal in most patients who present in the milder stages of COPD. When airflow limitation becomes severe, patients may have cyanosis of mucosal membranes, development of a barrel chest due to hyperinflation of the lungs, an increased resting respiratory rate, shallow breathing, pursing of the lips during expiration, and use of accessory respiratory muscles.

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- **Cough**: The most often first symptom of COPD is a chronic cough, which may or may not be productive of mucus as phlegm. An accompanying productive cough is only seen in up to 30% of cases. Sometimes limited airflow may develop in the absence of a cough. Symptoms are usually worse in the morning. When a cough persists for more than three months each year for at least two years, in combination with mucus production and without another explanation, it is by definition chronic bronchitis.[4]

- **Shortness of breath:** A cardinal symptom of COPD is the chronic and progressive shortness of breath which is most characteristic of the condition. Shortness of breath (breathlessness) is often the most distressing symptom. Shortness of breath is a source of both anxiety and a poor quality of life in those with COPD. [4] Shortness of breath is often responsible for reduced physical activity, and low levels of physical activity are associated with worse outcomes. In severe and very severe cases there may be constant tiredness, weight loss, muscle loss, and anorexia.

- **Exacerbations:** An acute exacerbation is a sudden worsening of signs and symptoms such as increased breathlessness, fast breathing, a fast heart rate, and sweating, active use of muscles in the neck, a bluish tinge to the skin, and confusion or combative behavior in very severe exacerbations.

- **Other conditions:** COPD often occurs along with a number of other conditions (comorbidities) due in part to share risk factor Common comorbidities include cardiovascular disease, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, depression, anxiety and lung cancer.
- Anxiety, depression and muscle wasting are often complications of COPD. Other complication include a reduced quality of life and increased disability, cor pulmonale, frequent chest infections including pneumonia, secondary polycythemia, respiratory failure, pneumothorax, lung cancer and cachexia.
- Cognitive impairment is common in those with COPD as it for other lung condition that affects airflow. Cognitive impairment is associated with the declining ability to cope with the basic activities of daily living.

DIAGNOSIS

- **Spirometry:** Spirometry measures the amount of airflow obstruction present and is generally carried out after the use of a bronchodilator, a medication to open up the airways. Two main components are measured to make the diagnosis, the forced expiratory volume in one second FEV1, which is the greatest volume of air that can be breathed out in the first second of a breath, and the forced vital capacity (FVC), which is the greatest volume of air that can be breathed out in a single large breath. Normally, 75–80% of the FVC comes out in the first second and a FEV1/FVC ratio less than 70% in someone with symptoms of COPD defines a person as having the disease. Based on these measurements, Spirometry would lead to over-diagnosis of COPD in the elderly. The National Institute for Health and Care Excellence criteria

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additionally require a FEV1 less than 80% of predicted. People with COPD also exhibit a decrease in diffusing capacity of the lung for carbon monoxide (D_{LCO}) due to decreased surface area in the alveoli, as well as damage to the capillary bed. [6]

- **Bronchodilator reversibility test:** test is performed when patients are clinically stable and free from respiratory infection. Patients should not have taken inhaled short acting bronchodilators in the previous six hours, long acting bronchodilator in the previous twelve hours or sustained release theophylline in the previous 24 hours. FEV1 should be measured before a bronchodilator is given. The bronchodilator should be given by metered dose inhaler through spacer devices or by nebulizer to be certain it has been inhaled. The bronchodilator dose should be selected to be high on dose-response curve. Possible dosage protocol are 400microgram beta2 agonist up to 160microgram anticholinergic or the two combined FEV1 should be measured again 10-15 minutes after a short acting bronchodilator is given , 30-45 minutes after the combination

- **Chest x-ray:** This exam can help to support the diagnosis of COPD by producing images of the lungs to evaluate symptoms of shortness of breath or chronic cough. While a chest x-ray may not show COPD until it is severe, the images may show enlarged lungs, air pockets (bullae) or a flattened diaphragm. A chest x-ray may also be used to determine if another condition may be causing symptoms similar to COPD.[6]

- **Chest computed tomography (CT) scan**: This exam may be performed to help support the diagnosis of COPD or determine if the disease has worsened. It combines special x-ray equipment with sophisticated computers to produce multiple images or pictures of the inside of the lungs. CT images can identify emphysema better and at an earlier stage than a chest x-ray. They can also identify other changes of COPD such as enlarged arteries in the lungs. CT is sometimes used to measure the extent of emphysema within the lungs. It can also help determine if the symptoms are the result of another disease of the chest. [7]

- **Sputum examination:** sputum examination is carried out if patient have productive cough. Sputum is the mucus that the patients cough. Analyzing of sputum to identify the causes of breathing difficulties and detect some lung cancers and also identified the bacterial infection.

- **Arterial blood gas test:** This test measures the oxygen (O_2) level in the blood and if carbon dioxide (CO_2) is removed properly. It can also determine the acidity (pH) of blood. Imbalances in the amount of oxygen, carbon dioxide, or pH can serve as a way to evaluate respiratory diseases, kidney function,. Results of the test can show the severity of COPD and whether a person needs oxygen therapy.[1]

STAGES/GRADES OF COPD

- **Mild COPD or Stage/Grade 1-** Mild airflow limitation (FEV1/FVC<70%; FEV1>80%) and sometimes, but not always, chronic and sputum production. At this stage, the individual may not be aware that his or her lung function is abnormal.
- **Moderate COPD or Stage/Grade 2-** Worsening airflow limitation (FEV1/FVC<70%; 50<FEV1<80% predicted), with shortness of breath typically developing during exertion. This is the stage at which patients typically seek medical attention because of chronic respiratory symptoms or an exacerbation of their disease.
- **Severe COPD or Stage/Grade 3-** Further worsening of airflow limitation (FEV1/FVC<70%; 30 %< FEV1<50% predicted), greater shortness of breath, reduced exercise capacity, and repeated exacerbation which have an impact on patient's quality of life.
- **Very Severe COPD or Stage/Grade 4—** Severe airflow limitation (FEV1/FVC < 70%; FEV1 < 30% predicted) or FEV1 < 50% predicted plus chronic respiratory failure. Patients may have Very Severe (Stage IV) COPD even if the FEV1 is > 30% predicted whenever this complication is present. At this stage, quality of life is very appreciably impaired and exacerbations may be life threatening.

THERAPEUTIC MANAGEMENT OF COPD

GOAL OF THERAPY:

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Prevention is the ultimate goal of COPD treatment. Once diagnosed, effective managements should be aimed at the following goals.

- Relieve symptoms
- Prevent disease progression
- Improve exercise tolerance
- Improve health status
- Prevent and treat complication
- Prevent and treat exacerbation
- Improve quality of life

NON – PHARMACOLOGICAL THERAPY:

- Smoking cessation is the most effective strategy to reduce the risk of developing COPD and the only intervention proven to affect the long-term decline in FEV1 and slow the progression of COPD.
- Pulmonary rehabilitation programs include exercise training along with smoking cessation, breathing exercises, optimal medical treatment, psychosocial support, and health education. Supplemental oxygen, nutritional support, and psycho educational care (e.g., relaxation) are important adjuncts in a pulmonary rehabilitation program.
- Annual vaccination with the inactivated intramuscular influenza vaccine is recommended.
- One dose of the polyvalent pneumococcal vaccine is indicated for patients at any age with COPD; revaccination is recommended for patients older than 65 years if the first vaccination was more than 5 years earlier and the patient was younger than 65 years.

PHARMACOLOGICAL THERAPY:
MEDICATION USED FOR COPD

CLASS	DRUG
Short acting beta 2 agonist (SABAs)	Albuterol , Levalbuterol
Long acting beta 2 agonist (LABAs)	Formoterol , Salmeterol
Short acting anticholinergic (SAMA)	Ipratropium bromide
Long acting anticholinergic (LAMAs)	Tiotropium bromide
Methylxanthines	Aminophylline , Theophylline
Inhaled corticosteroids (ICS)	Beclomethasone, Budesonide fluticasone
Combination of LABA+ICS	Formoterol/Budesonide Salmeterol/fluticasone Formoterol/mometasone
Phosphodiesterase(PDE4)inhibitors	Roflumilast

QUESTIONNAIRES USED FOR THE ASSESSMENT OF QUALITY OF LIFE

Quality of Life (QOL) measurements to quantify disease burden have become an important outcome measure in Chronic Obstructive Pulmonary Disease (COPD) re treatment. A large variety of QOL instruments is available.

- **St George respiratory questionnaire:** SGRQ is a self reported disease specific health related quality of life (QOL) questionnaire. It was originally developed to measure the impact of chronic obstructive pulmonary disease (COPD) on a person's life. [8]

It is also valid for use in bronchiectasis and has been used successfully in patients with kyphoscoliosis and sarcoidosis. It is in two parts. Part 1 produces the Symptoms scores and the part 2 the Activity and Impact scores. A total score is also produced. Scores range from 0 to 100, with higher scores indicating more limitations, and low score indicate better quality of life.

Structure of SGRQ

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Part 1(question 1-7) addresses the frequency of respiratory **symptoms**. It is not designed to be a precise epidemiological tool, but to assess the patient's perception of their recent respiratory problem.

Part 2(questions 8-14) addresses the patient's current state. The **Activity** score measures disturbances to daily physical activity. The **Impact** score covers a range of disturbances of psycho-social function [9].

- **Copd assessment test (CAT):** The CAT is a standard and validated test containing eight items for the evaluation of the impact of COPD on health status. It is a tool for the measurement of disease impact on health status, but FEV_1 is essential to establish a diagnosis and to confirm the severity of airway obstruction in symptomatic COPD patients. Range of CAT scores from 0–40. Higher scores denote a more severe impact of COPD on a patient's life.[10]
- **Clinical copd questionnaire (CCQ):** The Clinical COPD Questionnaire (CCQ) is recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) to evaluate health status in patients with COPD. The objective of CCQ to systemically assess the reliability, validity, responsiveness. The **CCQ** consists of three sub domains: symptoms, functional state and mental state. Items are **scored** on a Likert scale (range 0–60). The final **score** is the sum of all items divided by 10; separate scores for all three domains can be calculated. Higher scores indicate a worse health status.[11]
- **Chronic respiratory questionnaire (CCQ)**: The Chronic Respiratory Disease Questionnaire is a disease-specific health-related quality of life questionnaire. It was developed to measure the impact of Chronic Obstructive Pulmonary Disease (COPD) on a person's life. The CRQ includes four of dimensions: dyspnea, fatigue, emotional function, and mastery. In each area, scores are obtained by adding the scores for the items that make up each category and dividing it up by the number of items.[11]
- **Visual simplified respiratory questionnaire (VSRQ):** The Visual Simplified Respiratory Questionnaire (VSRQ) was designed to assess health-related quality of life (HRQoL) in patients with chronic obstructive pulmonary disease (COPD). It contains eight items: dyspnea, anxiety, depressed mood, sleep, energy, daily activities, social activities and sexual life. VSRQ scored from 0-80.[12]

QUESTIONNAIRES USED FOR THE ASSESSMENT OF MEDICATION ADHERENCE

- **Morisky medication adherence scale (MMAS-8):** The Morisky Medication Adherence Scale is a validated assessment tool used to measure non-adherence in a variety of patient populations. The Morisky Medication Adherence Scale is a valuable resource to address adherence concerns, such as forgetting to take medications or discontinuing medications without guidance. If a patient scores higher on the scale, they are evaluated as more adherent. If they score lower on the scale, they are presumed to be struggling with non adherence. By understanding how the patient scored on the scale, clinicians and health organizations can identify underlying issues that prevent patients from taking their medications correctly. MMAS score is 8 points, **<8 to >6 points** and ≤6 points on the scale is indicated as have high, medium and low adherence.[12]
- **Drug attitude inventory (DAI):** The DAI consists of a questionnaire that is completed by the patient. It includes a series of questions, each with true/false answers, pertaining to various aspects of the patient's perceptions and experiences of treatment. The original scale consists of 30 questions, but a short form consisting of 10 questions. The DAI-30 contains 15 items that a patient who is fully adherent to their prescribed medication would answer as 'True', and 15 items such a patient would answer as 'False'. To calculate the score from a set of answers, each 'positive' answer is given a score of plus one, and each 'negative' answer is given a score of minus one. The total score for each patient is calculated as the sum of the positive scores, minus the negative scores. A positive total score indicates a positive subjective response (adherent) and a negative total score indicates a negative subjective response (non-adherent).
- **Clinician rating scale (CRS):** The CRS uses an ordinal scale of 1–7 to quantify the clinician's assessment of the level of adherence shown by the patient. Higher numbers represent greater adherence. The CRS has been used in two controlled trials of 'compliance therapy', in which it demonstrated

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sensitivity in detecting differences in outcomes among patients receiving compliance therapy versus non-specific counseling.

III. METHODS

This prospective observational study was conducted for a period of one year from November 2020 to October 2021 in an in-patient and out-patient settings of a tertiary care hospital in Kerala. Interview questionnaires for socio-demographic as well as disease knowledge, medication adherence and QoL were used to collect data from 150 COPD patients from the Pulmonology Department of Tertiary care hospital.

Inclusion criteria

Inclusion criteria were both genders, patient diagnosed with COPD , patient should be in age group of > =18 and patients those who are willing to give informed consent.

Exclusion criteria

Exclusion criteria were severe organ failure (heart, liver, lung, kidney), mentally and retarded patients and pregnant and lactating women.

Study tools

Designed data collection form

Demographic details such as age, gender, and smoking status, and marital status, educational and occupational level are collected at the baseline along with SGRQ and MMAS-8 score in designed data collection form

Morisky medication adherence scale -8

It is used for assessing patient medication adherence related only on mediation usage during their treatment period. The questionnaire contains 8 questions which includes elements of forgetfulness, symptoms severity, other situational and emotional aspects of medications adherence. It's scoring indicates Yes=1 and No=0

St. George respiratory questionnaires

It is used for assessing health related quality of life. Disease specific measurements designed to identify the impact of overall health and perceived well-being in patients with chronic obstructive airway disease. It is divided into 2 parts. Part 1 (Symptoms): several scales; Part 2 (Activity and Impacts): True/False in which scoring ranges from 0 to 100, with higher scores indicating more limitations.

Other tools are patient medication chart, patient case report and patient information leaflet.

Study procedure

A designed patient data collection form was used to collect the baseline data along with SGRQ and MMAS-8 scale. Demographic details such as age, gender, marital status, educational and occupational level and smoking status and recorded in the data collection form. The subjects included in the study are grouped into intervention and control by using simple randomization technique. Pharmacist integrated care provided to the intervention group, which include Smoking cessation provide medication advice on inhaler technique and risk prevention advices (diet and exercise). Subjects are followed for the two follow ups and during each follow ups patient's quality of life and medication adherence were assessed. Quality of life is assessed by St George respiratory questionnaire and medication adherence is assessed by Morisky medication adherence scale-8.

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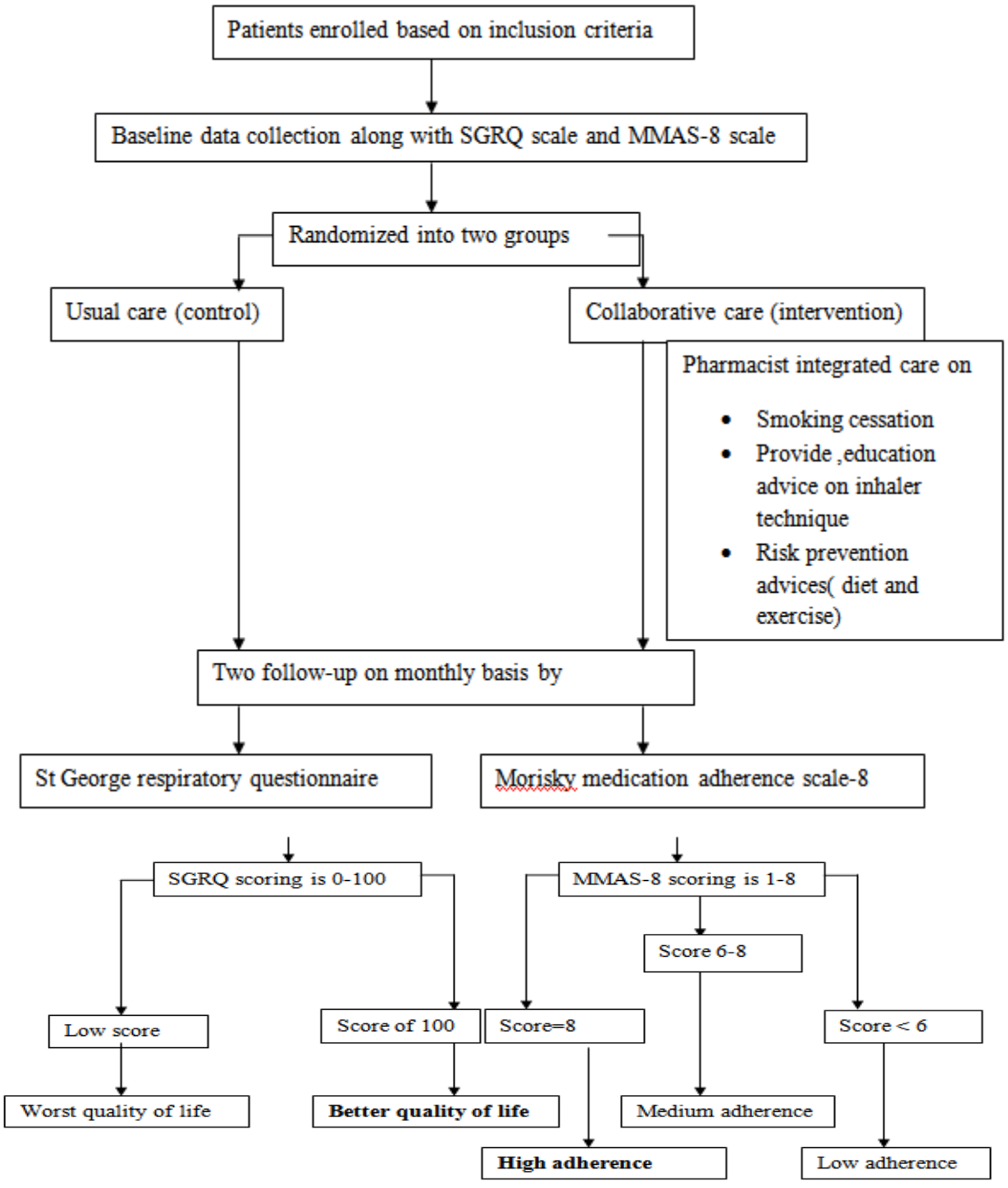

Statistical analysis

SPSS (statistical package for the social science) statistical software was used for statistical analysis. Chi- square test was used to find association between demographics. Paired t-test was used to assess the patient improvement in quality of life and medication adherence. Independent t-test was used to compare quality of life and medication adherence of both intervention and control group.

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IV. RESULTS

Table 1 :Demographic details of COPD patients

Age group	**Intervention (n=75)**	**Control(n=75)**
18-39	5(6.7%)	4(5.3%)
40-60	20(26.7%)	19(25.3%)
61-80	24(32%)	27(36%)
>80	26(34.7%)	25(33.3%)
Gender		
Female	25(33.3%)	24(32%)
Male	50(66.7%)	51(68%)
Smoking status		
Current smoker	21(28%)	24(32%)
Ex-smoker	29(38.7%)	27(36%)
Non-smoker	25(33.3%)	24(32%)
Educational level		
High	35(46.7%)	36(48%)
Low	40(53.3%)	39(52%)
Occupational level		
High	24(32%)	25(33.3%)
Low	40(53.3%)	39(52%)
Moderate	11(14.7%)	11(14.7%)
Marital status		
Married	71(94.7%)	72(96%)
Unmarried	4(5.3%)	3(4%)

Table 2:Changes in SGRQ scores at different time assessment

SGRQ scores	Intervention , Mean	Control Group, Mean
Symptoms		
Baseline	56	55
First follow-up	54.9	56
Second follow -up	53.9	57.1
Impact		
Baseline	59.1	56.7
First follow-up	57.7	59
Second follow -up	56.6	60
Activity		
Baseline	76.7	75.2
First follow-up	76.2	75.7
Second follow -up	75.8	76.4
Total		
Baseline	63.93	62.3
First follow-up	62.93	63.56
Second follow -up	62.1	64.5

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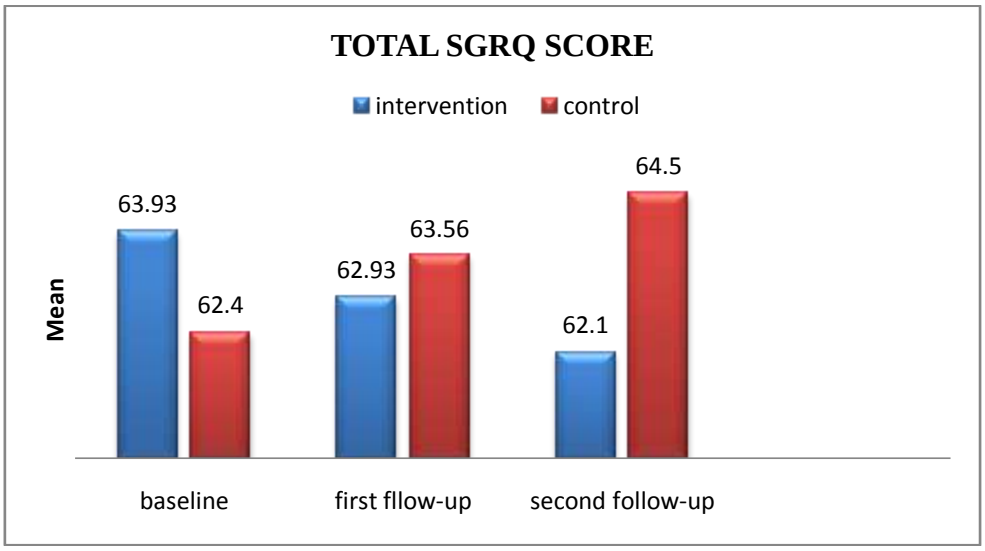

Fig 1: SGRQ total scores of both intervention and control

Table 3:Changes in MMAS-8 scores at different time assessment

MMAS-8 scores	Intervention(n=75)	Control (n=75)
Baseline		
Low adherence	41(54.7%)	39(52%)
Moderate adherence	19(25.3%)	21(28%)
High adherence	15(20%)	15(20%)
First follow up		
Low adherence	27(36%)	38(50.7%)
Moderate adherence	23(30.7%)	21(28%)
High adherence	25(33.3%)	16(21.3%)
Second follow up		
Low adherence	12(16%)	36(48%)
Moderate adherence	16(21.3%)	20(26.7%)
High adherence	47(62.7%)	19(25.3%)

REASON FOR NON-ADHERENCE

The most common reason for poor drug compliance in intervention and control group was feeling better (14.6%) and (12.82%). 51.21% participants in intervention and 25.64% participants in control revealed they stopped taking

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medication due to old age. Participants in forget to take medicine were 17.07% and 41.02% in intervention and control group and 12.19% and 12.82% due to fear of side effects. 4.80% in intervention and 7.69% in control had certain financial reasons

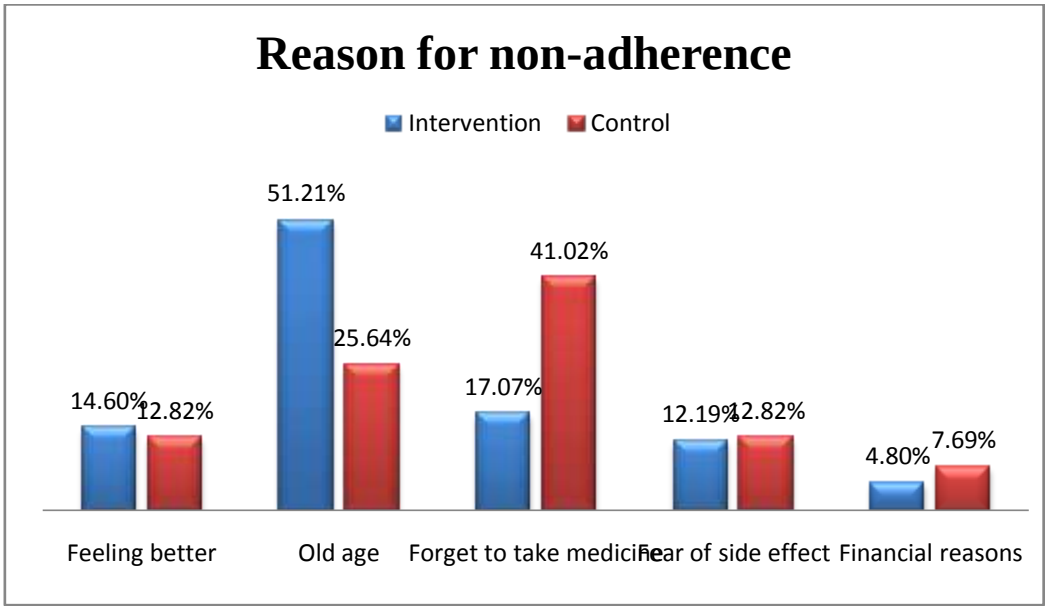

Fig 2: Percentage distribution of patients based on non adherence

ASSOCIATION OF AGE WITH SMOKING STATUS

From the obtained data, 5 non-smokers, 2 ex-smokers and 2 currents smokers were in the age group of 18-39. In age group of 40-60, 9 were non-smokers, 12 ex-smoker and 18 current smokers. In age group of 61-80, 24 patients were non-smoker, 13 were ex-smokers and 14 were current smokers and above 80, 11 were non-smoker, 29 ex-smokers and 14 current smokers. P –value is below 0.05 which indicate there is an association of age with smoking status.

Table 4: Association of age with smoking status

Age	Smoking status			Total	Chi-squared value	P-value
	Non smoker	Ex-smoker	Current smoker			
18-39	5	2	2	9	19.215	.003
40-60	9	12	18	39		
61-80	24	13	14	51		
Above 80	11	29	11	51		

ASSOCIATION OF GENDER WITH SMOKING STATUS

From the obtained data, 56 ex-smokers and 45current smokers were male and 49 non smokers were female. P value is below 0.05 which indicate there is an association between with gender and smoking status.

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Table 5: Association of gender with smoking status

Gender	Smoking status			Total	Chi-squared test	p-value
	Non-smoker	Ex-smoker	Current smokers			
Male	0	56	45	101	176.83	0.001
Female	49	0	0	49		

ASSOCIATION OF OCCUPATIONAL LEVEL WITH SMOKING STATUS

From the obtained data, 27 non-smokes, 33 ex-smokers and current smokers were in the low occupational level. In moderate occupational level, 3 were non-smokers, 7 ex-smokers and 12 current smokers and in high occupational level, 19 were non smokers, 16 ex-smokers and 14 current smokers. P value is above 0.05 which indicate there is no association of occupational level with smoking status.

Table 6: Association of occupational level with smoking status

Occupational level	Smoking status			Total	Chi-squared value	P-value
	Non smoker	Ex-smoker	Current smoker			
Low	27	33	19	79	8.798	0.063
Moderate	3	7	12	22		
High	19	16	14	49		

ASSOCIATION OF EDUCATIONAL LEVEL WITH SMOKING STATUS

From the obtained data, 27 non smokers, 33 ex-smokers and 19 current smokers were in low educational level and in high education level, 22 were non-smoker, 23 were-smokers and 26 current smokers. P value is above 0.05 which indicate there is no association of educational level with smoking status.

Table 7: Association of Educational level with smoking status

Educational level	Smoking status			Total	Chi-squared test	p-value
	Non-smoker	Ex-smoker	Current smokers			
Low	27	33	19	79	2.967	0.228
High	22	23	26	71		

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PAIRED T-TEST ANALYSIS OF SGRQ SCORES OF INTERVENTION GROUP

From the paired t-test analysis, the mean values of symptom from baseline to second follow up were (55.97 vs. 53.90, P-value<0.05), the mean values of activity from baseline to second follow up were (76.69 v s.75.76 P-value<0.05) and the mean value of impact score from baseline to second follow-up were (59.10 vs. 56.62, P-value<0.05). After two follow-ups the scores of the domains of symptoms, activities and impact in the intervention group were significantly improved, that means quality of life is improved in intervention group.. The best improvement was noted in the impact domain (59.10 vs. 56.62, P-value<0.05).

Table 8: Paired t-test analysis of SGRQ scores of intervention group

SGRQ	Mean	Std deviation	t	P- value
Symptom				
Baseline v/s First follow-up	55.97 54.89	3.411 3.313	11.219	0.001
First follow up v/s Second follow-up	54.89 53.90	3.313 3.110	14.661	0.001
Baseline v/s Second follow-up	55.97 53.90	3.411 3.110	17.218	0.001
Activity				
Baseline v/s first follow up	76.69 76.20	2.143 2.021	7.864	0.001
First follow up v/s Second follow-up	76.20 75.76	2.021 1.966	7.993	0.001
Baseline second v/s Second follow-up	76.69 75.76	2.143 1.966	9.373	0.001
Impact				
Baseline v/s First follow up	59.10 57.66	5.478 4.893	10.586	0.001
First follow up v/s Second follow-up	57.66 56.62	4.893 4.393	9.108	0.001
Baseline v/s Second follow-up	59.10 56.62	5.478 4.393	12.607	0.001

PAIRED T-TEST ANALYSIS OF SGRQ SCORES OF CONTROLGROUP

From the paired t- test analysis, the mean values of symptom from baseline to second follow up were (55.01 vs.57.07, P-value<0.05), the mean values of activity from baseline to second follow up were (75.23v s.76.39 P-value<0.05) and the mean value of impact score from baseline to second follow-up were (56.80vs.60.04, P-value<0.05). After two follow-ups there is no significant improvement in the scores of the domains of symptoms, activities and impact in the control group which indicate that, there is no improvement in the quality of life in control groups

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Table 9: Paired t-test analysis of SGRQ scores of control group

SGRQ	Mean	Std deviation	t	P- value
Symptom				
Baseline v/s First follow-up	55.01	3.087	15.90	0.001
	56.00	3.138		
First follow up v/s Second follow-up	56.00	3.138	13.51	0.001
	57.07	3.026		
Baseline v/s Second follow-up	55.01	3.087	22.07	0.001
	57.07	3.026		
Activity				
Baseline v/s first follow up	75.23	1.377	8.996	0.001
	75.70	1.442		
First follow up v/s Second follow-up	75.70	1.442	10.38	0.001
	76.39	1.702		
Baseline second v/s Second follow-up	75.23	1.377	11.21	0.001
	76.39	1.702		
Impact				
Baseline v/s First follow up	56.72	4.242	-12.17	0.001
	58.97	5.184		
First follow up v/s Second follow-up	59.04	5.180	-11.10	0.001
	60.04	5.287		
Baseline v/s Second follow-up	56.80	4.216	-15.61	0.001
	60.04	5.287		

COMPARISON OF SGRQ SCORES OF INTERVENTION AND CONTROL GROUP BY INDEPENDENT T-TEST ANALYSIS.

From the independent t-test analysis, the symptom mean value of intervention and control group after two follow-ups were (53.89 vs.57.07) and the activity mean value of intervention and

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control after two follow-ups were (75.75 vs.76.38) .The impact mean value of intervention and control after two –follow-ups were (56.62 vs. 60.04). By comparing the means of intervention and control groups, it shows the means are significantly different which indicates that there is an improvement in the domains of symptom, impact and activity of intervention group.

Table 10 : Comparison of SGRQ scores of intervention and control by independent t-test analysis

SGRQ		**Mean**	**Std deviation**	**t**	**P- value**
Symptom					
Second follow-up	Intervention	53.89	3.110403	-6.330	0.001
	Control	57.07	3.025566	-6.330	0.001
Activity					
Second-follow-up	Intervention	75.7573	1.96625	-2.094	0.038
	Control	76.3861	1.70231	-2.094	0.038
Impact					
Second follow-up	Intervention	56.62	4.393	-4.298	0.001
	Control	60.04	5.286	-4.293	0.001

PAIRED T-TEST ANALYSIS OF MMAS-8 SCORE OF INTERVENTION GROUP

From the paired t-test analysis, baseline mean of MMAS-8 score is 5.520, after two follow-up the MMAS-8 score were 7.240. It indicates that there is an improvement in the medication adherence of intervention group after 2nd follow-up.

Table 11: Paired t-test analysis of MMAS-8scores of intervention group

MMAS-8	**Mean**	**Std deviation**	**t**	**P- value**
Baseline	5.520	1.7271	-16.51	0.001
First follow-up	6.307	1.4517		
First follow -up	6.307	1.4517	-7.941	0.001
Second follow-up	7.240	1.1371		
Baseline	5.520	1.7271	-11.84	0.001

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Second follow-up	7.240	1.1371		

PAIRED T-TEST ANALYSIS OF MMAS-8 SCORE OF CONTROL GROUP

From the paired t-test analysis, baseline mean of MMAS-8 score is 5.253, after two follow-up the MMAS-8 score were 5.173. It indicates that the medication adherence of control group cannot be improved after second follow-up.

Table 12: Paired t-test analysis of MMAS-8 scores of intervention group

MMAS-8	Mean	Std deviation	t	P- value
Baseline	5.253	1.8966	-8.811	0.001
First follow-up	5.893	1.5732		
First follow -up	5.893	1.5732	-3.520	0.001
Second follow-up	5.173	1.4178		
Baseline	5.253	1.8966	-7.500	0.001
Second follow-up	5.173	1.4178		

COMPARISON OF MMAS-8 SCORE OF INTERVENTION AND CONTROL GROUP BY INDEPENDENT T-TEST ANALYSIS.

From the independent t- test analysis, the mean score of intervention and control group were 7.240 and 5.173. By comparing the MMAS-8 score of both group, the intervention group shown an improvement in the medication adherence

Table 13: Comparison of MMAS-8 scores of intervention and control by independent t-test analysis

MMAS-8	Mean	Std deviation	t	P- value
Intervention Second follow-up	7.240	1.1371	5.083	0.001
Control Second follow-up	5.173	1.4178	5.083	0.001

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V. DISCUSSION

The aim of the study was to determine the impact of pharmacist integrated care on quality of life of COPD patients. The main outcome of the study is to relieve that inclusion of pharmacist as team member in direct care can help to improve the patient's outcome like quality of life and medication adherence.

There were similar clinical characteristics and sociodemographics between the study participants at baseline. Most patients were elderly, males, married, ex-smoker, and low educational and occupational status. COPD was significantly higher among individuals who were 65 years or older. The high incidence rate among the patients who were 65 years or older is similar to the study conducted by **Selma et al** studied "the association between risk factors and chronic obstructive pulmonary disease in Canada: A cross- sectional study using the 2014 Canadian community health survey."[25]

Lund back et al studied "Not 15 but 50% of smokers develop COPD? Report from the obstructive lung disease in northern Sweden studies" [47] have found that almost 50% of smokers may develop COPD, which indicates that smoking is one of the major risk factors for the development of COPD. Therefore, there is a definite need to aware of the patients regarding the harmful effects of tobacco substances. In our study, the majority of the patients were past smokers (29 (38.7%) v/s 27(36%)), and therefore, it is very essential to impart counseling regarding the smoking cessation or avoidance of any kind of tobacco abuse.

Fig 2: showed that the most common reason for poor drug adherence was most poor drug compliance in intervention and control group was feeling better (14.6%) and (12.82%). 51.21% participants in intervention and 25.64% participants in control revealed they stopped taking medication due to old age. Participants in forget to take medicine were 17.07% and 41.02% in intervention and control group and 12.19% and 12.82% due to fear of side effects. 4.80% in intervention and 7.69% in control had certain financial reasons

The result from this study revealed that low medication adherence persist among COPD patients due to old age and forget to take medicine. This is in accordance with results obtained from previous **Tamas Agh et al** study that "factors associated with medication adherence in patients with chronic obstructive pulmonary disease" [49]

There was no significant trend toward an association between educational level and smoking status as shown in table 13 .The finding of present study were inconsistent with those of **Miriam et al** studied " the relationship of education attainment with pulmonary emphysema and airway wall thickness"[27]

COPD undoubtedly affects the ability of patients to perform normal daily activities, thereby affecting their quality of life. The SGRQ symptom scores of both intervention and control group after second follow up were (53.89 ± 3.1 vs 57.075 ± 3.02, $p<0.05$) , activity score (75.75 ± 1.96 vs. 76.38 ± 1.7 $p<0.05$) and impact score were (56.62 ± 4.3 vs. 60.04 ± 5.2 $p< 0.05$)After the first and second follow-ups, the scores of the domains of symptoms, activities, and impacts in the intervention group were significantly improved in intervention group , as shown in **table 16**

The findings of this present study on improved SGRQ scores in patients with COPD were inconsistent with those of **Xin et al** in Republic of China, the impact of pharmacist managed clinic on medication adherence and health related quality of life in patients with COPD: a randomized controlled study [23] and **Moses Jr et al** in the impact of clinical pharmacist intervention in chronic obstructive pulmonary disease management [18].

Patients suffering from chronic obstructive pulmonary Disease have an impaired quality of life especially on physical health compared with psychological and social health owing to the frequent experience of symptoms and limitations on their physical activities. Three main factors that are used in the SGRQ to govern the QOL are symptoms, activity, and impact. After intervention we found improved QOL in our study patients. We suggested that the clinical pharmacist intervention with more robust patient follow-up yields betterment in the quality of life in COPD patients.

The MMAS-8 score of intervention after two follow-ups were (7.240 ± 1.13, $p<0.05$) and control group were (5.173 ± 1.41, $p<0.05$). It showed that patient counselling improve medication adherence of intervention group, as shown in table **18.**

Based on our study data, a significant difference between the two groups in medication adherence after 12 months was noted, which was most likely attributed to the intensive education received by the intervention group. This is consistent with a 12 month study of **Xin et al** in

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Republic of China, the impact of pharmacist managed clinic on medication adherence and health related quality of life in patients with COPD: a randomized controlled study [23]. Therefore, positive health education can improve medication adherence of patients with COPD. A clinical pharmacist is well placed in the health care team to act as link between the physicians and the pharmacy

VI. CONCLUSION

The study focuses on the positive impact of health education and counseling provided by a clinical pharmacist in achieving better therapeutic outcomes through improvement in quality of life and medication adherence. The self-reporting questionnaire such as SGRQ and MMAS-8 method was found to be effective for the assessment of quality of life and medication adherence. . The reasons for non-adherence to the medication were resolved by patient counselling and hence, quality of life was improved which resulted in better patient health-related outcome. Clinical pharmacists must be considered as an integral element of healthcare system.

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