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Impact of Clinical Pharmacist Intervention on the Management of Health Related Quality of Life in Chronic Obstructive Pulmonary Disease

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***Abstract*: *Background:* Patient adherence to treatment in chronic obstructive pulmonary disease is essential to optimize disease management. Health-related quality of life is an important domain for measuring the impact of chronic disease.**

***Objectives:* The main objective of our study is to assess the health related quality of life and medication adherence: pre and post clinical pharmacist intervention.**

***Setting:* Respiratory Medicine Department of M.S. Ramaiah Hospitals, Bengaluru.**

***Methods:* A prospective interventional study was conducted. 96 subjects were recruited in the study based on inclusion criteria. Adherence to the treatment was assessed through Morisky-Greene-Levine scale. The health-related quality of life was assessed through SF-36. Reassessment of the above was conducted after 1-year span and the result was compared, evaluated and measured with appropriate statistics.**

***Results:* Participants in the high adherence category are 12.5% in the pre-counselling and 56.25% post-counselling. Highest correlation among SF-36 and Morisky-Greene-Levine scale was observed between pain and adherence (0.354). The level of $p<0.05$ was considered as significant.**

***Conclusion:* Medication adherence plays a key role in health-related quality of life in chronic obstructive pulmonary disease subjects. Statistically, significant improvement was observed in physical, general and social and emotional parameters.**

***Keywords*: COPD, HRQL, Medication adherence, MGL, SF-36, Clinical pharmacist.**

Abbreviations:
COPD: Chronic Obstructive Pulmonary Disease
HRQL: Health Related Quality of Life
MGL: Morisky-Greene-Levine scale
SF-36: Short Form-36
PFT: Pulmonary Function Test
GOLD: Global Initiative for Chronic Obstructive Lung Disease

1. Introduction

Chronic obstructive pulmonary disease is a common, preventable and treatable disease. It is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases [1]. Diagnostic symptoms of COPD basically include cough, sputum production and dyspnoea associated with airflow obstruction [2].

Smoking is the principal risk factor of COPD and is the reason behind approximately 85–90% of all cases [3]. Statistically, 10% to 15% of all smokers [4] and up to 26% of heavy smokers are at the high risk of developing this disease [5]. Globally, it is currently the fourth leading cause of death, with an overall prevalence rate between 4% and 10% [6]. By the year 2020, it is estimated that COPD will be the third leading cause of death [7].

Management of COPD is the most complex part. It requires patients to perform self-management practice that involves behavioural and lifestyle changes, such as smoking cessation, proper use of inhalers, adherence to suggested exercise and medications8. Adherence plays a crucial role in the management of COPD. There are various factors that affect medication adherence, such as patient perceptions of their disease, type of treatment, the quality of patient-health care provider communication and the social environment [9]. Patient adherence with longterm therapy in chronic diseases in developed countries is an estimate of 50%, according to the WHO [10]. The squander and additional costs associated with non-compliance are valued at US$ 300 billion annually [11]. Next to adherence, impairment in the health-related quality of life in patients with COPD had been reported in several studies [12]. A poor HRQL was shown to be associated with high levels of dyspnoea, physical impairment, depression and anxiety, a poor prognosis in terms of readmission to hospital and sub-optimal medication adherence [13].

A Clinical Pharmacist can assist through interventions focused on patient education about disease, prescribed medications and proper use of inhaler as well as appraisal of patient's willingness towards therapy [14]. Effectiveness of the intervention can be assessed in terms of improvement in health-related quality of life, medication adherence, disease knowledge and healthcare utilization. The present investigation intends to survey the effect of clinical pharmacist care on

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medication adherence and HRQL in COPD patients.

2. Materials and Methods

The effectiveness of the clinical pharmacist care intervention was assessed through a prospective, interventional study design with a 1-year follow-up. Patients who were admitted with the diagnosis of COPD in the wards of respiratory medicine, M. S. Ramaiah Hospitals were included in the study. Patients belonging to the age 35 years and above were considered15. Patients identified with mobility problems, confusion, disorientation, terminal illness, congestive heart failure were excluded from the study. Patients who had attended pulmonary rehabilitation programme, consulted a pulmonary nurse and/or clinical pharmacist in the last 6 months were also excluded. A total of 96 patients were considered based on the above criteria and all were given informed consent.

Baseline data for every patient was collected by the researcher pharmacist using a custom designed data collection form, from the medical charts, hospital computers and patient interviews. The collected data included demographic measures, spirometry measures, disease characteristics, treatment and history of exacerbations in the last 1 year. The patients along with their caretakers then completed a range of questionnaires in a face to face interview with the clinical pharmacist. They are:

MGL scale, a medication adherence assessment scale was used. It had 4 questions comprising of either "yes" or "no" as an answer.

SF-36, a set of generic, coherent, and easily administered quality-of-life measures questionnaire utilized for routine monitoring and assessment of care outcomes in adult patients was also administered. The patients were then assessed based on the answered questionnaires.

Structured patient education about COPD medications and the self-administration techniques, counselling necessary in relation to the mental and physical health, importance of a pulmonary rehabilitation in COPD, breathing exercises and finally the precautions to be taken from preventing the disease worsening any further was conveyed by the clinical pharmacist with a dummy inhaler and PIL's, along with the help of a pulmonary physiotherapist and a nursing staff. The information was imparted to the patient and the caretaker.

Follow-up of the baseline was conducted after a 1-year span and the data of the assessment and reassessment were compared, evaluated and measured.

Data collected at baseline and at the 1 year assessments were coded and entered into SPSS software version 17 for statistical analysis (data screening, descriptive statistics and univariate analysis). Data were examined using Chi-squared analysis, T-test, Pearson's correlation and P value of < 0.05 was considered statistically significant.

3. Results

A total of 96 COPD subjects were recruited into the study. Results indicated similar sociodemographic and clinical characteristics between the study participants. As shown in the Table 1, all of the subjects were males, of them maximum belonged to the geriatric population ≥60 (62.5%) years of age. The mean age was found to be 63.03 ±11.5.

Most of the study participants were current smokers with the duration of exposure being minimum of 10 years. Highest number of patients were in the range of 10 to 25 (41.67%) years duration.

Disease severity of all the random participants was categorized according to the PFT-GOLD classification of COPD. Maximum participants i.e., 82.29% were observed to fall under moderate category of COPD with a FEV1 of approximately 50% of the predicted normal value (Table 2).

A. Spirometry values

Spirometry, a lung function test was performed at the beginning of the study as a measure of lung capacity and so to assess the lung function. As observed in Table 3, there were no significant changes statistically among the study participants at baseline and over the study period.

B. Medication Adherence

Once the subject was counselled about the poor adherence to regimens resulting in severe health consequences, the Chi-square analysis at the 1-year assessment revealed a significant

Table 1
Baseline characteristics

Variables		Frequency (N)	Percentage(%)
	Adults (<60 years)	36	37.5
Age	Geriatrics (≥ 60 years)	60	62.5
Gender	Male	96	100
	Female	0	0
Occupation	Business	14	14.40%
	Engineer	7	7.29%
	Farmer	24	25.00%
	Finance	7	7.20%
	Health care	6	6.20%
	Marketing	1	1.00%
	Plumber	2	2.10%
	Shepherd	8	8.20%
	Teacher	10	10.30%
	Watchman	3	3.10%
	Worker wage	14	14.40%
Duration of smoking	10 to 25 years	40	41.67
	26 to 40 years	36	37.50
	>40 years	20	20.83

decrease in the proportion of non-adherent patients when compared to the pre-counselling(P<0.05). (Table 4).

Table 2
Pulmonary Function Test (PFT) - GOLD classification

GOLD staging	Number (n)	Percentage (%)
Mild (≥80%)	0	0.00%
Moderate (50% to 80%)	79	82.29%
Severe (30% to ≤ 50%)	17	17.71%

Table 3
Spirometry

Spirom-etry	Mean	Std. Deviation	Std. Error Mean	T test	P value
Baseline	60.28	9.056	0.924		
1 year	58.34	9.899	1.010	1.421	0.445

Table 4
Pre-Post value of Morisky-Greene-Levine scores among study participants

Variables		Pre	Post	Chi-square	Sig. 2 tailed
M1	YES	48(50.0)	5(05.2)		*0.031*
	NO	48(50.0)	91(94.8)	10.265	
M2	YES	48(50.0)	10 (10.4)	14.784	*0.001*
	NO	48(50.0)	86(89.6)		
M3	YES	48(50.0)	5(05.2)	10.265	*0.031*
	NO	48(50.0)	91(94.8)		
M4	YES	72(75.0)	88(91.7)	4.845	*0.04*
	NO	24(25.0)	08(8.3)		

Chi square test, sig. 2 tailed, p<0.05

Table 5
Pre-Post value of SF-36 scores among study participants

Domains		Mean	Std. Deviation	t value	Sig. 2 tailed
Pair 1	General health	1.531	1.256	11.944	*.000*
Pair 2	Limitations of activities	-6.573	1.999	-32.222	*.000*
Pair 3	Physical & Emotional health problems	-1.990	2.003	-9.734	*.000*
Pair 4	Social activities	.823	.725	11.115	*.000*
Pair 5	Pain	2.010	1.192	16.525	*.000*
Pair 6	Energy and emotions	1.708	1.297	12.904	*.000*
Pair 7	Social activities & General Health	-1.354	1.265	-10.491	*.000*

Paired t test, sig.2 tailed, p<0.05

Table 6
Correlation r-value pre & post counselling MGL & SF-36 scores among study participants

Correlation pre-counselling		Pre M	Post M
General health	r- value	-.167	.047
	Sig. (2-tailed)	.103	.646
Limitations of activities	r- value	.049	.051
	Sig. (2-tailed)	.636	.619
Physical health problems	r- value	.067	.111
	Sig. (2-tailed)	.517	.282
Social activities	r- value	.009	-.090
	Sig. (2-tailed)	.928	.384
Pain	r- value	.354**	.086
	Sig. (2-tailed)	.001	.402
Emotions and energy	r- value	.020	-.149
	Sig. (2-tailed)	.843	.148
General health pre	r- value	.037	.267**
	Sig. (2-tailed)	.724	.008
Pre M	r- value		
	Sig. (2-tailed)	1.000	-
Post M	r- value		
	Sig. (2-tailed)	-	1.000
**. Correlation is significant at the 0.01 level (2-tailed).	*. Correlation is significant at the 0.05 level (2-tailed).		

Table 7
Pearson's correlation

Correlations pre & post		PRE M	POST M	SF-6 PRE	SF-6 POST
MGL	Pearson Correlation	1	0.000	0.100	0.080
	Sig. (2-tailed)		1.000	0.331	0.440
	Pearson Correlation	0.000	1	0.217*	0.222*
	Sig. (2-tailed)	1.000		0.034	*0.029*
SF-36	Pearson Correlation	0.100	0.217*	1	0.896**
	Sig. (2-tailed)	0.331	*0.034*		*.001*
	Pearson Correlation	0.080	0.222*	0.896**	1
	Sig. (2-tailed)	0.440	*0.029*	*0.001*	
*. Correlation is significant at the 0.05 level (2-tailed).					
**. Correlation is significant at the 0.01 level (2-tailed).					

Table 8
Hospitalization due to exacerbation

Exacerbation	Mean	Std. Deviation	Std. Error Mean	T test	P value
PRE	1.06	0.455	0.046	11.41	*0.002*
POST	0.84	0.530	0.054		

C. Health-related quality of life (SF-36)

A significant improvement especially in the domains of physical and emotional health of the subjects clueing on the impact of an intervention on the behavioural enhancement. (Table 5).

D. Correlation of Adherence & HRQL

As shown in Table 6 & 7, the r-value and Pearson's correlation was applied to assess the statistical difference in the correlation between the pre and post counselling drawing the importance of the medication adherence in the maintenance of quality of life and how this has an impact on overall day to day health and social activities of the subjects.

E. Hospitalization due to exacerbation

Admissions to the emergency or hospitals were assessed at the baseline and the follow up mainly to signify the difference in the number of visits pre and post counselling. The P value 0.002 proving once again the importance of the joint package of an intervention and medication adherence in the improvement of the health related quality of life.

4. Discussion

In this study, 96(100%) patients were males. This might be because of higher exposure rate to primary risk factor(smoking) in male participants. The reason could be negligence or ignorance towards the disease by females. This observation is in contradiction with the findings of a study on gender related difference in clinical presentation of COPD by Jain NK [16] et.al., study included 702 patients of COPD of which 493 (70.2%) were males and 209 (29.8%) females. In comparison to males, females reported more dyspnoea at presentation (grade 3 v/s grade 2, $P < 0.001$). This could be due to females displaying more bronchial obstruction than males (mean FEV_1 of 43.39 ± 13.28 v/s 48.42 ± 14.52, respectively, $P < 0.001$). This could also be related to the increased susceptibility of Indian females to etiological agents (tobacco and biomass smoke) or delay in the diagnosis of COPD in females at primary health care level and/or late referral to a tertiary care hospital (which may be due to knowledge gap regarding COPD in females and/or less use of spirometry to diagnose or grade COPD severity).

Men have higher prevalence rates of chronic obstructive pulmonary disease (COPD) than women, which had been attributed to the historically higher rates of cigarette smoking in males. Common Indian man starts smoking at the age between 20-30 years and it takes at least 10-15 years of smoking habits to develop COPD [16]. From the current study 62.5% of the total population were found to be from the age group ≥60 years. This is in concordance with a study conducted by P. Sawant [17] et.al., which revealed that a maximum number of COPD patients were from age group 61-70 years with minimum age being 34 years to be diagnosed. Chronic obstructive pulmonary disease (COPD) is a progressive disease and its symptoms usually develop late over the years; hence COPD may be more commonly seen in elderly.

Demographic data of the sample showed that the common risk factor for all the 96 patients was smoking for a minimum period of 10 years. In this study 41.67% were chronic smokers for over a period of 10 to 25 years. In the next range of 26 to 40 years there were 36 participants making up to 37.50% of the total and there were 20 participants with a duration of above 40 years which makes up to 20.83% of the total sample. This is in line with the study conducted by Llordés M [18] et.al., where a population based study was conducted in a primary care centre among subjects older than 45 years with a history of smoking. The participants underwent a clinical questionnaire and spirometry with bronchodilator test. One out of four smokers 45 years or older presented in primary care have airflow obstruction, mostly undiagnosed. The prevalence of COPD was 24.3% (95%, CI 22.3–26.4), with an overall under diagnosis of 56.7%. Patients with COPD were older, more frequently male.

In a total of 96 subjects with COPD, farmers (25%) were most affected compared to other occupations in the study group. This may be due to either their impaired lifestyle or lack of knowledge regarding the disease, medication and medication techniques. This is in line with the study conducted by Guillien A [19] et.al., a cross-sectional study of 917 non-farming working controls and 3787 farmers aged 40–75 years. Where, respiratory symptoms, tobacco exposure, job history (without direct exposure measurement) and lung function was being assessed. The prevalence of COPD in farmers was found to be higher (5.1%) when compared to non-farming working controls (2.9%).

Medication adherence is defined as the extent to which a patient's medication taking behaviour coincides with the intention of the health advice they had been given. Adherence is one of the most important factors that determine therapeutic outcome, especially in patients suffering from chronic illness like COPD [20]. Pharmacists are in a unique position to improve medication adherence because they can actually show the medication to the patient and provide any information related to the medication [21]. In the current study Morisky-Greene-Levine scale which consists of four "yes or no" questions was used to measure the medication adherence. The pre and post counselling correlation and the statistical significance of the adherence was assessed with the chi-square test. The correlation co-efficient value [$p<0.05$] values as mentioned in Table 4 shows the significant statistical difference in the pre and the post pharmacist counselling values in the adherence. Similar to a study conducted by Faheemuddin MD [22] et.al., it was found that there was no significant difference at baseline, but followed by first follow up was <0.01, followed by second follow up <0.0001. This clearly showed that there was a good improvement in medication adherence behaviour of COPD patients who underwent intervention when compare to control because the intervention group patients were provided with effective counselling materials.

HRQL is a multidimensional construct that generally includes assessments of physical, mental, and social functioning. The measurement of HRQL can be approached using general or disease-specific instruments. Short Form-36 is the questionnaire used to measure the HRQL in the patients generally. It comprises of 36 items divided into eight domains.

In the current study the significant improvement in the patient HRQL between the pre and post counselling values had been statistically established through paired t-test and Pearson's test {($p<0.05$), (Table 5)}. This is in concordance with the study conducted by Khdour MR [23] et.al., where over the 12-month period in the intervention group, Emergency Department(ED) visits decreased by 50% (P= 0.02) and hospitalization by approximately 60% (P= 0.01). On the SGRQ, differences reached statistical significance on the symptom (−7.5; P= 0.04) and impact (−7.4; P= 0.03) subscales but not on the physical activity subscale.

The Pearson's correlation was assessed to estimate a statistical significance of the correlation between the adherence to medication and the health related quality of life. The correlation was significant at the level of $p<0.05$ and $p<0.01$ proving the statistical reliability of the data. Unlike the study conducted by Esteban C [24] et.al., on the Use of medication and quality of life among patients with COPD which states that the SF-36 showed greater deterioration in the areas of physical functioning (PF), role physical, general health, and vitality, although no significant differences were found in other areas. In the SF-36, differences are found only in PF domain. Our study showed quite a significant correlation between the medication adherence and the HRQL and is statistically relevant based on the values in Table 6.

Study limitations:

The study was limited in the time required to complete the set of questionnaires used in the present study may have encouraged bias in the responses gained from the participants, as in an effort to finish quickly, participants may have answered without giving much consideration to the questions. Also, recall bias associated with the use of a face to face questioning method to assess medications adherence could affect the results. Inclusion was limited to male patients only, as no females were admitted within the study period.

5. Conclusion

Improved patient outcomes as a result of the pharmaceutical care programme were obtained in the present study. This was justified by decreased hospital admission rates, significant improvement in medication adherence and enhanced positive attitudes toward medication effectiveness. The present study therefore clearly stated the need to implement pharmaceutical care programmes by the clinical pharmacists for the purpose of improving health outcomes in patients with COPD. More comprehensive research is needed in this area, particularly the impact of such pharmaceutical care programmes on the health-related quality of life for patients with COPD and other chronic disorders.

Ethics Approval

The ethical clearance (EC/Ph-13/2018) for the study was obtained from the ethics committee (Reg. No. ECR/215/Inst/ KA/2013/RR-16) of M. S. Ramaiah Medical College and Hospitals, Bangalore-560054, Karnataka, India.

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