Prospective Observational Study on Assessing Medication Reconciliation and Health-related Quality of Life for Chronic Obstructive Pulmonary Disease: Emerging Role of Pharmacists

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ABSTRACT

Aim and background: Chronic obstructive pulmonary disease (COPD) is a sustained obstructive airway disease that impedes normal breathing function. The most effective course of action, as deemed by clinical pharmacists, is the implementation of pulmonary rehabilitation, analyzing patient medication charts, efficacy, and safety of medications, improving/enhancing the quality of life, counseling or educating patients, etc. The aim of the present study is to evaluate medication discrepancies and provide counseling to patients to gauge the impact of pulmonary rehabilitation on their health-related quality of life (HRQoL).

Materials and methods: A prospective observational study was conducted for 6 months in the Department of General Medicine and Respiratory at a tertiary care hospital. Patients aged >18 years who admitted having a history of COPD were recruited. Further, the best possible medication history (BPMH) was noted, and patients were counseled to compare the quality of life in COPD patients in the pretest and posttest using the SF-36 HRQoL questionnaire. The statistical method used was the dependent t-test.

Results: A total of $N = 185$ patients were screened in accordance with the study's criteria, and $N = 103$ were enrolled. We identified that the most significant variations occurred when bronchodilator dosage schedules were prescribed upon discharge, and comparisons were made to measure quality of life. In the follow-up, there was an improvement in all domains of quality of life. The pre- and posttest scores were subjected to comparison, and an enhancement in the quality of life was documented (p-value: 0.0001).

Conclusion: This study explains the pharmacist's intervention in poststudy. A significant decrease in discrepancies was found, and counseling patients helped improve the quality of life among COPD patients.

Clinical significance: This study signifies the emerging role of clinical pharmacists in reviewing medication charts, identifying and resolving drug related problems, and educating patients to improve their quality of life.

Keywords: Clinical pharmacist, Chronic obstructive pulmonary disease, Counseling, Medication discrepancy, Quality of life.

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is constantly rising in incidence with age. COPD is the leading cause of morbidity worldwide, mainly in developing countries. It is an obstructive and progressive lung illness, a major decline in physical activity, and other symptoms that contribute to the patient's disability and poor HRQoL.[1]

Chronic obstructive pulmonary disease (COPD's) typical symptoms, such as shortness of breath, cough, fever, and chest tightness, seriously impact patients' lives, especially those of individuals with severe COPD. Commonly reported symptoms include breathlessness as a result of the distinctive lung hyperinflation seen with the disease and greatly reduced exercise tolerance.[2] Morning symptoms make it difficult for patients to perform daily tasks and morning practices, and they may be linked to an increased frequency of exacerbations.[3]

Clinical pharmacists are registered healthcare professionals who are essential in the evaluation of patients, analysis of prescriptions, promotion of quality of life and medication adherence, educating patients, the development of drug regimens, sensitivity to medications, detection of adverse

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drug reactions, and providing education to patients to stop smoking.[4–6]

Patients with COPD have a demented quality of life, which worsens disease conditions and lowers socioeconomic status, resulting in lower patient quality of life. The pharmacist's role in

patient counseling for COPD patients is to help them learn about prescription drugs and dosages and enhance their overall health.[7,8]

As a result, this is the key to removing obstacles that arise during hospital stays and enhancing the patient's health. It is important to understand the positive and negative factors that influence pharmacist intervention to increase the benefits to COPD patients.[8,9]

Very few studies have been conducted on COPD patients in India. Thus, this study was conducted to minimize discrepancies and improve quality of life by educating patients about disease, medication, and lifestyle modification.[9,10]

This study signifies that clinical pharmacists play an essential role in helping patients comprehend their prescriptions, improving the effectiveness of their medications, educating patients, diagnosing any allergic conditions, and reducing hospital readmission.[11] Medication reconciliation gives COPD patients additional knowledge about the medications they are taking, as well as how, when, and why to take them. Instructing patients on the proper use of inhalers and other devices can also be helpful along with these PR programs, which support patients in eradicating exacerbation symptoms through dietary, physical, and psychological intervention. Hence, these all together are a standard approach for improving HRQoL and benefiting patients with COPD.[12]

MATERIALS AND METHODS

Ethical Clearance
The Ethics Committee (KLE/COP/2021 - 22/674), KLEs Dr Prabhakar Kore Charitable Hospital, and Medical Research Center, Belagavi, approved the study protocol.

Study Design and Setting
At a tertiary care hospital in Belagavi, Karnataka, a prospective observational study was conducted in the Department of General Medicine and Respiratory Department.

Inclusion Criteria

- Patients who were diagnosed with COPD and treated with one of the following medications during treatment: short-acting β-2 agonist, short-acting muscarinic antagonist, long-acting muscarinic-antagonist, methylxanthines, long-acting β-2 agonist, and corticosteroid combinations
- Patients aged >18 years of age.
- Patients who were willing to participate in the study voluntarily gave, written, signed, and dated informed consent form (ICF).

Exclusion Criteria

- Patients diagnosed with human immunodeficiency virus, cancer, and coronavirus disease of 2019 (COVID-19).
- Patients who had impaired cognitive function.
- Patients who were pregnant or expected to become pregnant during the following 6 months.

Study Procedure
The study was conducted at a tertiary care hospital in Karnataka (Fig. 1).

Step 1: Patients who fit the inclusion criteria were approached and asked to take part in the study, and their consent was obtained.

Step 2: The patient's medication history was taken. Compiled a comprehensive list of medicines the patient was taking.

If the patient brought his/her own list and it matches with a medical record or the patient/caregiver explained all discrepancies.

- Confirmed patient's preadmission medication list with one or more sources.
- Reconciled [best possible medication history (BPMH)] with prescribed medication.
- Identified discrepancies using the criteria mentioned.
- Appropriate information about medications to avoid discrepancies was provided.

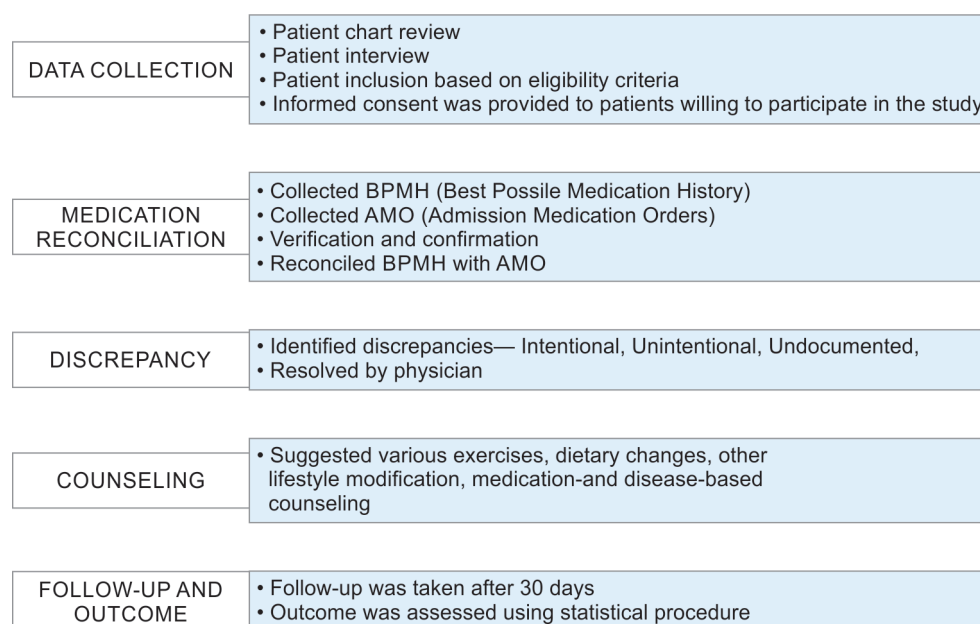Step 3: The SF-36 questionnaire was used for assessing the patient's HRQoL.

| DATA COLLECTION | • Patient chart review
• Patient interview
• Patient inclusion based on eligibility criteria
• Informed consent was provided to patients willing to participate in the study |

| MEDICATION RECONCILIATION | • Collected BPMH (Best Possile Medication History)
• Collected AMO (Admission Medication Orders)
• Verification and confirmation
• Reconciled BPMH with AMO |

| DISCREPANCY | • Identified discrepancies— Intentional, Unintentional, Undocumented,
• Resolved by physician |

| COUNSELING | • Suggested various exercises, dietary changes, other lifestyle modification, medication-and disease-based counseling |

| FOLLOW-UP AND OUTCOME | • Follow-up was taken after 30 days
• Outcome was assessed using statistical procedure |

Fig. 1: Schematic diagram

Step 4: Counseled patient individually about their medications, diet, and exercises to avoid further exacerbations of COPD.

Statistical Methods

Dependent and independent *t*-test.

Level of Significance

A *p*-value of <0.0005.

RESULTS

A total of *N* = 185 patients were screened for the study; *N* = 103 of these patients, 55.67%, met the eligibility requirements and were enrolled. Based on exclusion criteria, the remaining 82 (44.32%) patients were not included in the study. Of 82 patients, six passed away due to respiratory failure and other comorbid conditions, 10 had a history of COVID-19, 10 patients were planning to be pregnant, and 25 patients had serious comorbid conditions like uncontrolled type 2 diabetes mellitus, lung carcinoma, cardiovascular diseases, etc. The remaining seven patients were preparing to relocate away from the study site, and 24 individuals were unwilling to participate in the study. Patient demographic details, including age, gender, occupation, qualification, socioeconomic status, habits, and locality where they were staying, were gathered using data collection forms.

During their admission to the hospital, patients were counseled regarding lifestyle modification, pharmacological therapy, nonpharmacological therapy, habitual changes, and precautions to avoid risk factors and explained the usage of inhalers.

The pre- and postinterventions were made based on medication discrepancies, HRQoL was assessed at the time of follow-up, and a comparison was made.

Demographic Profile

The majority of patients were males, 68.93%, and the remaining 31.07% were females. Of these, 58.25% of patients had a history of smoking, and 41.75% were nonsmokers. A total of 56 patients (54.37%) of the 103 total patients gathered were aged between 61 and 70 years old, with a mean age of 66.08 observed.

Among 103 patients, 45 had shortness of breath, 35 had a cough, nine had fever, and 14 had chest tightness. These were typical symptoms that were observed as chief complaints of the patients (Fig. 2).

Occupational Status

Here, it is observed that 55% of people were farmers; 32% were laborers, carpenters, and industrial employees; and the remaining 13% were tailors, electricians, and company owners, among other occupations. The therapy of the disease and identifying the primary etiological factors that led to the disease are significantly influenced by the occupational exposure of COPD patients (Fig. 2).

Educational Status

The management of the condition is significantly influenced by the patient's level of literacy. The patients were informed about their condition and treatment options. For this reason, a patient's basic knowledge is crucial to enhance their state of health. Most patients had only received their primary education (33%), secondary education (10%), illiteracy (54%), and graduation (3%) (Fig. 2).

Locality of the Patients

The location and domicile of the patients may have an impact on the disease's causation. In this case, 68% of the people were from rural areas, and 32% were from urban places. Therefore, the study shows that persons in rural areas are more likely to contract an infection than people in urban areas (Fig. 2).

Socioeconomic Status

The socioeconomic level of the patients has an impact on their quality of life as well. Low socioeconomic level affects both management of the disease and quality of life. In our study, 88% of participants had low socioeconomic status, defined as having an income of <15,000 rupees per month, and 11% had excellent socioeconomic status, defined as having an income of between 15,000 and 30,000 rupees (Fig. 2).

Medication Discrepancies

Medication reconciliation is a process in which healthcare providers, along with patients and their families, make sure medication information is transferred accurately and completely. This process involves obtaining the most complete and accurate list possible of medications the patient was taking regularly, that is, the BPMH.
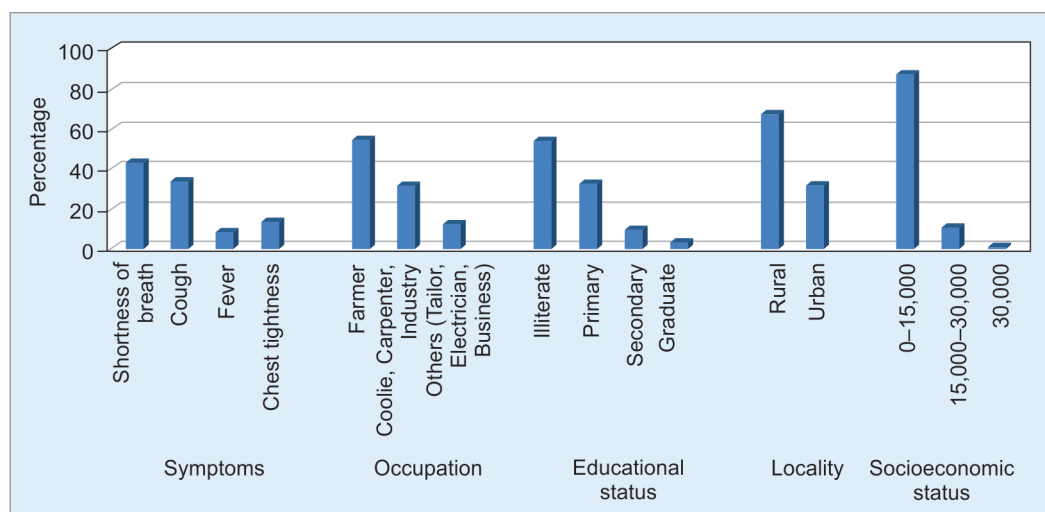

Fig. 2: Distribution of patients

Using and comparing the BPMH with admission or discharge medication orders helps in identifying any discrepancies.

The goal of medication reconciliation is to prevent adverse drug reactions and to eliminate intentional, unintentional, and undocumented discrepancies. An intentional discrepancy is when the prescriber makes an attempt to meet patients' needs with documentation of the intended change in the clinical record. Unintentional discrepancy occurs when the prescriber unintentionally changes, adds, or omits a medication a patient was taking prior to hospitalization. Undocumented discrepancy occurs when a prescriber intentionally adds, changes, or discontinues a medication, but it is not clearly documented in the patient's medical record.

While looking for discrepancies, it was found that 60.19% of patients had no discrepancies, which did not require any intervention. In 14.56% of patients, it was seen there were intentional discrepancies. Undocumented were in 5.38% of patients,

and in 19.42%, there were unintentional discrepancies in prescribing the dosing schedule of bronchodilators at discharge (Table 1).

Health-related Quality of Life

All nine domains' scores are included in the overall mean HRQoL score. Quality of life cannot be gauged or evaluated solely by one term. It covers everything related to general health, activity restrictions, emotional well-being, physical activity, emotional vs social activities, pain, allergies, and emotions and social activities. Thus, quality of life, along with medication and exercises, plays an important role in treating COPD patients.

In the present study, pre- and posttest results of QOL are described by the figures in terms of mean value. The overall mean HRQoL score in the pretest was 50.04, and the posttest was 58.98. However, the mean difference at the follow-up was found to be 8.94. This signifies that there was an increase in the quality of life

Table 1: Type of discrepancies and their association with smokers and nonsmokers

	Number of patients		Percentage of patients	
Type of discrepancy	Admission	Readmission	Admission	Readmission
No discrepancy	62	70	60.19	67.96
Intentional	15	11	14.56	10.67
Undocumented	6	5	5.83	4.85
Unintentional	20	17	19.42	16.5
Total	103	103	100.00	100.00

Association between smoking status and type of discrepancy						
Type of discrepancy	Smoker	%	Nonsmoker	%	Total	%
No discrepancy	37	59.68	25	40.32	62	60.19
Intentional	7	46.67	8	53.33	6	5.83
Undocumented	3	50.00	3	50.00	6	5.83
Unintentional	13	65.00	7	35.00	20	19.42
Total	60	58.25	43	41.75	103	100.00

Table 2: Pretest and posttest scores compared for HRQoL by dependent *t*-test

Variables	Test	Mean	Standard deviation (SD)	Mean difference	SD difference	Percentage of change	t-value	p-value
Domain 1: general health	Pre	44.90	28.30	−10.07	19.65	−22.43	−5.2019	0.0001*
	Post	54.98	20.74					
Domain 2: limitations of activities	Pre	57.92	25.50	−13.05	17.47	−22.54	−7.5814	0.0001*
	Post	70.97	20.84					
Domain 3: physical health problems	Pre	47.84	30.29	−7.14	18.75	−14.93	−3.8653	0.0002*
	Post	54.98	27.53					
Domain 4: emotional health problems	Pre	37.59	13.20	−6.68	41.82	−17.77	−1.6211	0.1081
	Post	44.27	42.86					
Domain 5: social activities	Pre	54.85	23.24	−11.17	25.18	−20.35	−4.5005	0.0001*
	Post	66.02	24.47					
Domain 6: pain	Pre	45.24	21.92	−16.89	17.01	−37.34	−10.028	0.0001*
	Post	62.14	22.35					
Domain 7: energy and emotions	Pre	52.27	16.32	−5.305	7.95	−9.67	−6.4521	0.0001*
	Post	57.32	14.53					
Domain 8: social activities	Pre	62.52	28.39	1.55	14.19	2.48	1.1107	0.2693
	Post	60.97	28.47					
Domain 9: general health	Pre	47.21	28.93	−9.79	12.62	−20.75	−7.8762	0.0001*
	Post	57.00	16.41					

*Signifies p-value of less than 0.05- significant study

after patient counseling and education. The study shows positive outcomes after counseling and educating them (Table 2).

In each of the domains, there is an increase in mean value in the posttest as compared to the pretest. The pretest and posttest scores were compared, and a significant increase in quality of life was reported (*p*-value of −0.001).

General Health

Focuses on assessing the patient's state of complete emotional, mental, and physical well-being. In order to reduce the risk and burden of disease, maintaining a healthy lifestyle is important for overall general health. The endurance of a person's respiration and heartbeat, as well as their muscular strength, flexibility, and body composition, can all be developed by maintaining physical fitness. Domain 1 also improved significantly. The pretest score was 44.90, and the posttest score was 54.98 (difference is 10.07) (*p*: 0.0001).

Limitation of Activities

Due to risk factors of COPD, it may lead to patients limiting performing usual activities. Running, lifting large things, engaging in physically demanding activities, as well as moderate tasks like moving a table, carrying groceries, climbing stairs, and taking a shower. The 10 questions in this domain are structured using the terms above. Most of the patients do not have any limitation to carry out activities after follow-up (domain 2, *p*: 0.0001).

Physical Health Problems

Various physical health problems can lead to increased time required for completing tasks, limiting the type of work or activities, difficulty in performing work, etc. These criteria are used to measure the physical health of the patient. It is always observed that having good physical health is to perform daily activities smoothly (domain 3). The mean score increased; that is, the pretest score was 47.84, and the posttest score was 54.98.

Emotional Health Problems

Any emotional problems such as feeling depressed or anxious that may affect the amount of time required to complete work or other activities or accomplish less work than expected or less careful than usual to complete the task. It has always been seen that having good emotional health leads to a healthy and good life in completing activities on time. The above domain consists of three questions depending on the emotional health of the patient; the mean difference observed in the pretest and posttest was 6.68. It was also seen in the patient posttest that the patient had an improved state of mind in terms of emotional health (domain 4).

Social Activities

This domain is concerned with emotional problems that interfere with social activities with family, friends, neighbors, or groups. There was a significant difference between the pretest and posttest mean scores for emotional vs. social health in our study, with a mean difference of 11.17. Of the clinical approach and counseling made to the patient, there was a significant increase in the mean in the posttest (domain 5).

Pain

This domain focuses on the amount of pain the patient had in the last 4 weeks and how much the pain affected daily activities. The mean score increased in the posttest, and the mean difference was found to be 16.89. Thus, pain plays an important role in living a good quality of life. As we know, pain is directly proportional to performing daily activities; the pain increases in difficulty performing daily activities. Thus, with the pharmacist's approach, the mean score increased in the posttest (domain 6).

Energy and Emotions

This domain involves focusing on nervousness, feeling pep, feeling down, feeling calm and peaceful, having the energy to focus on daily activities, feeling downhearted, and being happy all the time. It includes nine questions related to the above terms. Focusing on energy can help the patient improve overall quality of life, accept the disease's severity, and improve management of the disease. The mean score of the pretests was 52.27, and the posttest was 57.32 (the difference is 5.305). There is a significant difference in the posttest score after intervention (domain 7).

Social Activities

This domain involves the patient's physical health/emotional problems interfering with social activities (visiting friends and relatives). It has one question related to the above concern, and the mean score of pretests was 62.52, and the posttest score was 60.97 (the difference is 1.55).

General Health

This involves questions related to overall health, such as if the patient falls sick easily and if the patient has not accepted the disease and thinks it might worsen with time. It has four questions about the terms mentioned above. The mean score of the pretest was 47.21, and the posttest was 57 (the difference is 9.79). There is a difference in posttest after pharmacists' approach toward patient care.

Association between Age and Gender with Smoking Status

There is an association between gender and smoking status, as 76.06% of male patients were smokers, and only 18.75% were female patients. Therefore, it demonstrates that male subjects are more prone to develop the disease. Thus, exposure to smoking, dust, and pollutants can worsen COPD and lead to more complications (Fig. 3).

Association between Smoking Status and Type of Discrepancy

When smoking status and the type of discrepancy were compared, smokers made up 59.68% of patients, while nonsmokers made up
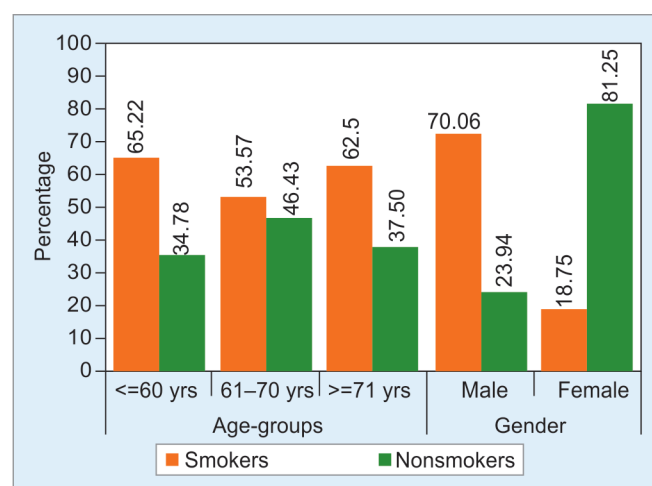

Fig. 3: Association between age and genders with smoking

Table 3: Comparison of smokers and nonsmokers with pre- and posttest scores of HRQoL and its domains by independent *t*-test

| Variables | Treatment times | Smokers | | Nonsmokers | | |
		Mean	SD	Mean	SD	t-value
HRQoL	Pretest	52.35	13.47	46.82	12.14	2.1399
	Posttest	59.65	15.37	58.05	15.97	0.5152
	Difference	7.31	9.02	11.23	11.95	1.8989
Domain 1	Pretest	45.42	30.18	44.19	25.78	0.2166
	Posttest	54.38	21.32	55.81	20.11	0.3458
	Difference	8.96	19.81	11.63	19.56	0.6781
Domain 2	Pretest	61.68	27.38	52.67	21.86	1.7854
	Posttest	71.67	20.68	70.00	21.27	0.3986
	Difference	9.99	15.26	17.33	19.56	2.1370
Domain 3	Pretest	51.88	33.02	42.20	25.32	1.6111
	Posttest	58.34	27.48	52.77	23.78	1.0729
	Difference	6.47	19.05	10.57	19.53	1.0662
Domain 4	Pretest	37.86	13.79	37.22	12.49	0.2420
	Posttest	44.00	42.94	45.58	42.70	0.1847
	Difference	6.14	40.70	8.36	43.40	0.2659
Domain 5	Pretest	59.17	22.06	48.84	23.75	2.2697
	Posttest	67.08	23.24	64.53	26.30	0.5194
	Difference	7.92	23.69	15.70	26.74	1.5575
Domain 6	Pretest	48.04	22.86	41.34	20.16	1.5407
	Posttest	63.25	21.42	60.58	23.76	0.5956
	Difference	15.21	14.46	19.24	20.16	1.1838
Domain 7	Pretest	53.94	17.85	49.92	13.79	1.2363
	Posttest	58.55	14.85	55.61	14.05	1.0128
	Difference	4.60	8.08	5.68	7.81	0.6800
Domain 8	Pretest	65.33	28.96	58.60	28.75	1.1663
	Posttest	64.0	28.00	58.60	27.74	0.9682
	Difference	−1.33	16.82	0.00	15.74	0.4074
Domain 9	Pretest	47.81	17.25	46.37	15.08	0.4418
	Posttest	55.63	16.10	58.92	16.84	1.0061
	Difference	7.81	11.83	12.56	13.30	1.9062

40.32%. Intentional differences were among the patients, of which 46.67% smoked and 53.33% did not. There were undocumented discrepancies in 50% of smokers and 50% of nonsmokers. Unintentional discrepancies were seen in 65% of smokers and 35% of nonsmokers (Table 1).

Association between Smoking Status and HRQoL

Smoking Status vs HRQoL

Patients with a smoking habit had a poor quality of life as compared to nonsmokers. In the posttest, it was observed that the patient who stopped smoking had an improved quality of life as smoking leads to difficulty breathing (Table 3).

Discussion

Aryal et al. conducted a study on COPD and gender difference where the sample size was 130, 60% of whom were men and the rest females. In our study, it was observed that the most affected population by COPD was the geriatric population, and among them, 68.93% (71) were male, and 31.07% (32) were enrolled in the study. Literature and studies have proven that males are more prone to develop COPD, and

the same was observed in our study, which shows that risk factors like gender play a vital role in the exacerbation of COPD.[13]

In a study on the impact of occupational exposures like dust, fumes, vapors, and gas, Diaz-Guzman et al. analyzed data from a WHO study conducted in 2000 and found that certain occupational risk factors account for 13% of all cases of COPD. In our study, it was estimated that in 55% of all cases, the occupational background of these individuals was farmer, which shows there is an association between exposure and dust and the development of COPD.[14]

As smoking is an important causative factor for the development of this condition, there is evidence that the progression of COPD and the risk of developing the disease can be reduced by cessation of smoking. Rafael Laniado-Laborin conducted a study about the relationship between smoking and the progression of COPD. Epidemics of the 21st century among the population 65% of smokers had exacerbation of COPD as compared to nonsmokers. In our study, 58.25% of the population were smokers, 41.75% were nonsmokers, and all the patients with a history of smoking had an exacerbation of COPD.[15]

Thalla et al. conducted a study that included 197 patients; among these, 119 were from the inpatient department (IPD), and

78 were from outpatient department (OPD), wherein 167 males, among which 97 from IPD, 70 from OPD, and females were 30 among which 22 from IPD, eight from OPD showed that smoking habit, exposure to dust, minerals, etc., leads to an increased risk of acute exacerbation of COPD. In our study, we included 103 patients; among them, 71 were males and 32 were females, showing patients who had smoking habits and farmers by occupation were at high risk of developing COPD.[16]

Eisenhower conducted a study on the impact of pharmacist-conducted medication reconciliation; six patients had medication discrepancies, and these were reported, and four patients were readmitted within 30 days of discharge. It concluded that medication reconciliation at discharge decreased discrepancies for patients with exacerbation of COPD. In our study, medications were reconciled, and during admission, 62.19% of patients were without any discrepancies, 14.56% were intentional, 5.83% were undocumented, and 19.42% had unintentional discrepancies, and during readmission comparatively 67.96% of the patients had no discrepancies, 10.67% were intentional which has been reduced, 4.85% were undocumented and 16.5% were unintentional discrepancies, this demonstrates that pharmacist-conducted medication reconciliation has a positive impact on patient care in hospital settings.[17]

Manen et al. conducted a study to evaluate the impact of COPD on HRQoL; it was assessed with the help of an SF-36 questionnaire and concluded that impairment in physical health, bodily pain, and general health is related to COPD while social and emotional health is not impaired due to COPD. During our study, in the pretest, almost all the domains of HRQoL are impaired, but in posttest scores, it is observed that after counseling, the quality of life has been improved in general health, physical health, and social health. Patients can perform daily activities, and body pain has also reduced.[18]

After completion of the study, we conclude that the clinical pharmacist approach to medication reconciliation helps in determining the type and number of medication discrepancies and plays a very significant role in providing information to the patient about disease severity, drug–drug interactions, or drug-food interactions, dietary and lifestyle changes to improve the overall health of the patients. It is evident in the pre- and posttest individuals who participated in this study increased their quality of life after participating. Thus, counseling and educating patients regarding the disease helped to improve the overall quality of life among COPD patients.

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