

The Burden of Chronic Obstructive Pulmonary Disease COPD in Stable Patients and its Association with Inflammatory Biomarkers and Body Mass Index

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a progressive airflow limitation that is preventable but not curable. It is associated with persistent symptoms that cause a considerable burden on individual productivity at work, and daily activities, and reduced quality of life, also burdening the healthcare system and society.

Objectives: The study aims to measure the burden of COPD on patients in terms of daily activities and work productivity. It also seeks to investigate some inflammatory biomarkers' levels and their correlation with selected outcomes.

Patients and Methods: A cross-sectional study on 120 stable COPD patients who were diagnosed and treated according to the GOLD guidelines at Kirkuk General Hospital's chest and Internal Medicine consultation clinics, and in private internist clinics in Kirkuk City, Iraq between January and April 2023. The Work Productivity and Activity Impairment Questionnaire (WPAI-COPD) measured the Burden of COPD. The symptom burden was assessed by the COPD assessment test (CAT). The level of IL-6 monoclonal antibodies was measured via a Roche Cobas 6000 analyzer and TNF- α using the ELISA sandwich technique. All these devices and machines were authorized by the Ministry of Health, Iraq. **Results:** The mean age was (54.1 \pm 8.12) years, 62.5% being males and 37.5% being females; 41.7% were public sector employees, and 39.2% were self-employed. Due to COPD, the overall work loss was (45.9 \pm 18.91) days, the mean percentage of absenteeism was (10.9% \pm 12.31%), activity impairment was (47.5% \pm 17.79%) among all patients, presenteeism was (40.8 \pm 15.05%), and COPD-related retirees were 14.2% of the study group. The mean CAT score (19.3 \pm 5.63) was high and the most troubling symptom among patients was chest tightness. WPAI-COPD scores were higher in older age and longer disease duration. The levels of biomarkers were above the reference ranges, the mean IL-6 level was (69.4 \pm 35.29) pg/ml, and the mean TNF- α was (72.3 \pm 22.45) pg/ml.

Conclusions: COPD patients exhibit a disease burden in terms of productivity loss at work and activity impairment that increases with aging and disease duration. COPD patients with low BMI are more prone to a decline in lung functions and to worse symptoms.

Keywords: Disease burden, COPD, productivity, tumor necrosis factor- α , interleukin- 6.

Introduction:

Chronic Obstructive Pulmonary Disease COPD is a progressive respiratory condition that imposes a significant burden on patients. It is characterized by chronic productive / non-productive coughing, wheezing, and dyspnea which is the hallmark sign of COPD and a significant contributor to the disease's impairment and anxiety (1). It is expected that by 2030, COPD will be the third most common cause of mortality globally, accounting for 3 million deaths yearly, and over 10% of people worldwide will suffer from COPD. (2,3). Increased rates of smoking, indoor and outdoor air pollution, and other exposures, together with aging, increase the burden and prevalence of COPD (4). Cytokines and chemotactic factors that compromise the immune system are secreted excessively due to infections,

smoking, air pollution, and other reasons. Previous studies showed that the inflammatory damage caused by inflammatory reactions is the main contributor to the progression of COPD (5). In Iraq, two recent studies have paid more attention to asthma and its management, assessing asthmatic patients' response to different medication regimens (6,7). Another study compared treatment regimens and their influence on the quality of life of pediatric asthmatics (8), and another one assessed the effects of pharmacist counseling for asthmatic children to ensure correct inhaler use (9). Another study addressed problems associated with inhaler shortages and adherence to treatment guidelines and the assessment of Iraqi doctors' compliance with treatment guidelines (10). Not much is known about the burden and the immunological complications caused by COPD in the Iraqi population. A prior study examined this issue and found that the quality of life is significantly deteriorated as a result of

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COPD (11). Further research examined type 2 diabetes mellitus (T2DM) prevalence in patients with severe COPD and showed that they are more likely to have T2DM (12). Another study addressed the prevalence of COPD among smokers over 40 years of age (13). Employees with COPD have an approximately five-fold increase in work productivity loss and a three-fold increase in activity impairment compared to those without COPD (14). It is important to examine the influence of COPD on patients' everyday activities, and work environment, which is not currently done in Iraq. The goal of this study is to describe COPD burden among stable cases in terms of everyday activity and impact on work productivity, with a focus on exploring the relationship between symptoms burden and work productivity with essential biomarkers involved in COPD inflammatory response.

Patients and Methods

This is a cross-sectional study on 120 COPD-stable patients who attended the Department of Respiratory Diseases and Internal Medicine consultation clinic at Kirkuk General Hospital, Kirkuk City between January and April 2023. Inclusion criteria were patients > 18 years of age, already diagnosed by the pulmonologist since at least one year according to the GOLD criteria (a post-bronchodilator FEV1/FVC ratio <0.7), and clinically stable. Patients who refused to perform a pulmonary function test (PFT) or had a disease exacerbation that needed systemic corticosteroid, antibiotic treatment, or an emergency department visit in the previous three months and had any medical condition that impacted quality of life were excluded. Verbal consent was obtained from all patients. Data Collection Tool: A questionnaire form was used to collect clinical and demographic variables (age, gender, work status, level of education, employment status, disease duration, smoking index, and comorbidities). Pulmonary function test (PFT): The procedure is done using spirometry under a skilled technician's supervision. After 15 minutes of bronchodilator inhalation (short-acting agonist, 4×100 µg salbutamol) via a spacer device, a post-bronchodilator test was carried out. A test with forced expiratory volume in the first second / forced vital capacity (FEV1/FVC) ratio <70% confirmed the diagnosis of COPD (1). Body mass index (BMI): Is measured by dividing weight by height square (kg/m²) and is categorized as: Underweight (<18.5), normal (18.5–24.9), overweight (25.0–29.9), obese (≥30)". Biomarkers level: Blood interleukin-6 (IL-6) is determined using Roche Cobas 6000 analyzer, elecsys IL-6 kit (ref. code 05109442190) and tumor necrosis factor alpha (TNF-α) is determined using ELISA sandwich technique, and TNF-α Camilo biological kit. COPD assessment test: disease symptoms were assessed using the Arabic version of the (CAT) questionnaire, a short validated, and easy-to-use self-administered questionnaire to evaluate the impact of COPD symptoms on the patient's life. It includes eight items

(cough, sputum production, dyspnea, chest tightness, self-confidence leaving home, activity, sleep, and energy level). Each item has a score of 5, with total ratings ranging from 0 to 40. The CAT questionnaire score is presented as a percentage (0 - 100%). Higher scores reflect a greater impact of illness on the health status and a greater symptom burden (15). Work Productivity and Activity Impairment Questionnaire (WPAI): The impact of COPD on work productivity was assessed by the Arabic version of the (WPAI-COPD) Questionnaire which is a reliable tool to estimate the burden of COPD in terms of work and activity impairments in the previous seven days prior to the study. The WPAI generates four scores presented as percentages: Activity impairment, presenteeism (impact of illness on work performance), overall work productivity loss (combined impact of absenteeism and presenteeism), and absenteeism (hours missing from work due to COPD), with larger values reflecting greater impairment and poorer productivity (16).

Statistical analyses:

SPSS v 25 was used for data analysis. Descriptive statistics were conducted for demographic and clinical characteristics of the disease. Continuous variables were expressed as (means ± standard deviation SD), whereas categorical variables were expressed as percentages and frequencies. To determine the correlations between the continuous variables, the Pearson correlation was utilized. A P-value of less than 0.05 was considered statistically significant.

Results:

Demographic characteristics of the participating patients

The mean age of the patients was (54.1 + 8.12) years. Males constituted 62.5% of the cases. The majority (86.7%) were married, and 47.5% had a college degree or above. Three-quarters were urban residents. Most of the respondents were employed with (41.7%) working for the government, (39.2%) with private employment, and 14.2% were COPD-related retirees. Former smokers constituted (56.7%) and (20%) were current smokers, table 1.

Table 1: Demographic characteristics of the participating patients

Characteristics	Subcategories	Frequency	Percent
Gender	Male	75	62.5
	Female	45	37.5
Marital status	Married	104	86.7
	Unmarried	16	13.3
Education	Illiterate	16	13.3
	Primary school	15	12.5
	Secondary school	32	26.7
	College or higher	57	47.5
Residence	Urban	91	75.8
	Rural	29	24.2
Employment status	Governmental job	50	41.7
	Private job	47	39.2
	Housewife	5	4.2

	Retired due to COPD	17	14.2
	Unemployed	1	.8
Smoking status	Current smoker	24	20.0
	Ex-smoker	68	56.7
	Never smoked	28	23.3

Clinical parameters of the participating patients: The mean age of the patients was (54.1 ±8.12) years. The mean COPD duration was (7.5 ±3.71) years, and the duration of treatment was (4.8 ±3.0) years. The mean BMI was (24.1 ± 3.97 kg/m²), with a range of (16.3–30.5kg/m²). The lung function tests (FEV1 and

FEV1/FVC ratio) of the participating patients were below the normal range. Biomarker levels were elevated: The mean IL-6 level was (69.4 ±35.29) and the mean TNF-α level was (72.3±22.45). The mean of work time loss (absenteeism) due to COPD was 10.9% ± 12.31%, and patients estimated presenteeism (productivity loss at work) was 40.8% ± 15.05%, for an estimated 45.9% ± 18.91% overall work impairment. Activity impairment is seen in (47.5% ±17.79%) of stable COPD patients, table 2.

Table 2: Clinical parameters of the participating patients

Variable	N	Minimum	Maximum	Mean	SD
Age (year)	120	31	68	54.1	8.12
BMI (kg/m ²)	120	16.3	30.5	24.1	3.97
Pack-years smoking	96	24	50	39.4	4.74
Disease duration (years)	120	2	15	7.5	3.71
Treatment duration (months)	120	2	24	4.8	3.00
IL-6 (pg/ml)	120	5.60	142.40	69.4	35.29
TNF-alpha (pg/ml)	120	32.80	128.40	72.3	22.45
FEV1	120	38.80	82.20	60.4	11.06
FEV1 /FVC	120	40.20	69.00	62.9	5.42
CAT score	120	8.00	32.00	19.3	5.63
Work time (hours)	97	40.00	70.00	47.0	6.97
Actual work time (hours)	97	27	60	41.9	8.29
Absenteeism (% per week)	97	0.00	41.00	10.9	12.31
Presenteeism (% per week)	97	10.00	60.00	40.8	15.05
Activity impairment	120	10.00	80.00	47.5	17.79
Overall work loss score	97	10.00	76.00	45.9	18.91

Assessment Test (CAT): COPD

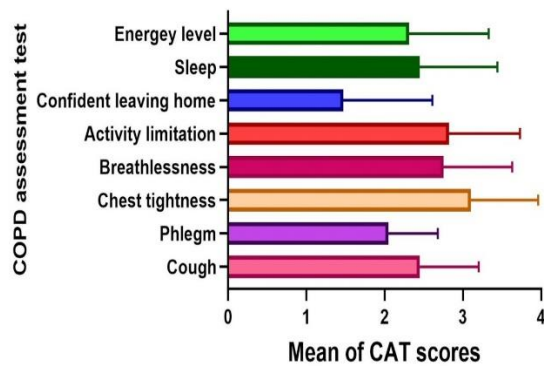


Figure 1: Means of the eight items of the COPD Assessment Test

The mean (CAT) score was (19.3 ±5.63) (Table 2). On average, the majority of patients felt tight chests and were limited in their ability to walk upstairs and do activities at home. On the other hand, the majority felt confident leaving home despite their lung condition (Figure 1).

The correlations between patient characteristics and WPAI-COPD outcomes: Patient age and disease duration had significant positive correlations, while BMI had significant negative correlations with absenteeism, presenteeism, activity impairment, and overall work loss. In other words, old age and longer COPD disease duration are associated with absenteeism, presenteeism, activity impairment, and overall loss job. In contrast, lower BMI is associated with greater loss of function, table 3.

Table 3: The correlations between patient characteristics and outcome measures

Patient characteristics		Actual work time	Absenteeism	Presenteeism	Activity impairment	Overall work loss score
Age (year)	Pearson Correlation	-0.148	0.320	0.448	0.421	0.455
	P-value	0.147	0.001*	0.000*	0.000*	0.000*
BMI (kg/m ²)	Pearson Correlation	0.203	-0.262	-0.281	-0.399	-0.287
	P-value	0.046*	0.010*	0.005*	0.000*	0.004*
pack-years Smoking	Pearson Correlation	0.096	0.057	0.146	0.223	0.119
	P-value	0.405	0.619	0.202	0.029*	0.301
Disease duration	Pearson Correlation	-0.338	0.473	0.667	0.750	0.638
	P-value	0.001*	0.000*	0.000*	0.000*	0.000*

*Significant at P<0.05 level

The correlations between patient characteristics and the disease biomarkers, lung function tests, and CAT:

The BMI also had significant negative correlations with IL-6, TNF-alpha, FEV1, FEV1 /FVC, and CAT scores. Patient age and disease duration had similar significant correlations with the five parameters: two biomarkers, two lung function tests, and a CAT score, table 4.

Table 4: The correlations between patient characteristics and the disease biomarkers, lung function tests, and CAT

Patient/disease characteristics		IL-6	TNF-alpha	FEV1	FEV1 /FVC	CAT score
Age (year)	Pearson Correlation	0.368	0.214	-0.366	-0.258	0.406
	P-value	0.000*	0.019*	0.000*	0.004*	0.000*
BMI (kg/m ²)	Pearson Correlation	-0.458	-0.729	0.438	0.465	-0.497
	P-value	0.000*	0.000*	0.000*	0.000*	0.000*
Smoking index	Pearson Correlation	0.225	0.439	-0.204	-0.194	0.163
	P-value	0.028*	0.000*	0.046*	0.058	0.113
Disease duration	Pearson Correlation	0.635	0.387	-0.676	-0.586	0.726
	P-value	0.000*	0.000*	0.000*	0.000*	0.000*
Treatment Duration	Pearson Correlation	-0.159	-0.087	0.109	0.119	-0.221
	P-value	0.083	0.345	0.237	0.196	0.015*

*Significant at P<0.05 level

Discussion:

The findings of this study indicate that even in stable cases, COPD places a significant burden on patients to perform everyday life activities and tasks, resulting in productivity loss at work. Symptom burden (CAT score 19), mainly chest tightness, had a significant impact on health status, restricted the patient's activity and performance of household tasks, and resulted in poor productivity. This not only affects the patients but also disturbs the work environment. Consistent with our result, a study done on mild and moderate airflow obstruction demonstrated that decreased job productivity was more common in COPD patients with a high symptom burden (17). In consistence with the findings of Foo et al (18), our findings showed a significant loss in work productivity of COPD participants who had greater degrees of dyspnea and other symptoms. The current study showed that work productivity loss, activity impairment, and missed hours at work increased as the age and duration of disease increased, I agreement with a study done in Korea (19). Age-related changes in lung structure and function in COPD patients are accompanied by a reduction in the effectiveness of the pulmonary protective mechanisms against oxidative stress, which enhances the risk of lung infections, all leading to a decline in lung function (20). Additionally, owing to aging reduced muscle mass causes a decrease in muscular strength, which in turn causes a decline in exercise tolerance (21). In COPD patients

with low BMI, a decline in lung functions (FEV1, FEV1 /FVC) and CAT score was detected, with patients with lower BMI showing greater productivity loss, impairment in activity, and absenteeism. This agrees with other studies that suggested that one of the risk factors for accelerated deterioration in lung function is a low BMI (22). Studies demonstrated that a low BMI is a significant prognostic factor in patients with COPD. BMI reduction in COPD should be carefully monitored, as it is linked to exacerbations and increased mortality (23). COPD is an inflammatory process in which the levels of TNF-α and IL-6 are elevated in stable COPD patients and associated with an increase in age and disease duration. This finding is consistent with previous studies which showed that many inflammatory mediators are released even in stable COPD condition such as IL-6 released from endothelial cells, fibroblasts, and epithelial cells and macrophages releasing TNF-α which can damage lung structure and worsen lung functions (24,25). The BMI of the participants was shown to be negatively correlated with their TNF-α level, which is consistent with the findings of Webster et al. which showed that TNF-α releases nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) which causes atrophy in the skeletal muscles (26).

Conclusion

COPD patients exhibit a disease burden in terms of productivity loss at work and activity impairment that increases with aging and disease duration. COPD patients with low BMI are more prone to a decline in lung functions and to worse symptoms.

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Authors' declaration:

Conflicts of Interest: None

We hereby confirm that all the Figures and Tables in the manuscript are ours. Besides, the Figures and images, which are not ours, have been given permission for re-publication attached to the manuscript.

Ethical Clearance: The project was approved by the local ethical committee in Kirkuk General Hospital, Iraqi Ministry of Health (according to code 952.14-12-2022). In addition, approval of the ethical board College of Pharmacy, University of Baghdad according to the code number (REAFUBCP7122022).

Author Contributions:

Study conception & design: (Ali L. Jasim). Literature search: (Samaa D. Ibrahi). Data acquisition: (Samaa D. Ibrahi). Data analysis & interpretation: (Samaa D. Ibrahi). Manuscript preparation: (Samaa D. Ibrahi). Manuscript editing & review: (Ali L. Jasim).

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عبء مرض الإنسداد الرئوي المزمن لدى المرضى المستقرة حالتهم وارتباطه بالمؤشرات الحيوية الإلتهابية

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1 فرع الصيدلة السريرية، كلية الصيدلة، جامعة بغداد، بغداد، العراق

الخلاصة:

خلفية البحث: م مرض الإنسداد الرئوي المزمن (COPD) هو تقييد تدريجي لتدفق الهواء يمكن الوقاية منه ولكن لا يمكن علاجه. ويرتبط بالأعراض المستمرة التي تسبب عبئاً كبيراً على إنتاجية الفرد في العمل، والأنشطة اليومية، وانخفاض جودة الحياة، مما يتقل كاهل نظام الرعاية الصحية والمجتمع..

الأهداف: تحديد عبء مرض الإنسداد الرئوي المزمن على المرضى من حيث الأنشطة اليومية وإنتاجية العمل وقياس مستوى بعض المؤشرات الحيوية الإلتهابية ودراسة العلاقات المحتملة بين النتائج المختارة.

المنهجية: تم إجراء دراسة مقطعية على 120 من مرضى مرض الإنسداد الرئوي المزمن المستقرين الذين تم تشخيصهم بالفعل من قبل المتخصصين في عيادات الصدر والباطنية الإستشارية في مستشفى كركوك العام، وكذلك العيادات الباطنية الخاصة في مدينة كركوك، العراق. بدأت الدراسة في شهر كانون الثاني ولغاية شهر نيسان من سنة 2023. وتم قياس عبء مرض الإنسداد الرئوي المزمن من حيث النشاط وضعف الإنتاجية في العمل من خلال إستبيان ضعف إنتاجية العمل والنشاط (WPAI-COPD) وعبء الأعراض الذي تم تقييمه بواسطة إختبار تقييم مرض الإنسداد الرئوي المزمن (CAT). تم قياس مستوى IL-6 باستخدام محلل Roche Cobas 6000 و TNF- α باستخدام تقنية ELISA Sandwich.

النتائج: كان متوسط العمر (54.1 ± 8.12) سنة وأغلبية المرضى من الذكور (62.5%) وإناث. نسبة المرضى العاملين لدى الحكومة (41.7%)، والمرضى العاملين في القطاع الخاص (39.2%)، إجمالي فقدان العمل (بسبب التغيب وقلة الإنتاجية) هي (45.9 ± 18.91). متوسط نسب التغيب عن العمل (10.9 ± 12.31 %)، وقلة النشاط خلال العمل هو (47.5 ± 17.79 %). متوسط نسبة قلة الإنتاجية خلال العمل هي (40.8 ± 15.05 %). إجمالي نسبة المتقاعدین بسبب مرض الإنسداد الرئوي المزمن هي 14.2%. كانت درجة تقييم عبء الأعراض مرتفعة (19.3 ± 5.63 ، وكان العارض الأكثر إثارة للقلق بين المرضى هو ضيق الصدر. وكانت درجات الإنتاجية خلال العمل وضعف النشاط أعلى في كبار السن ومع زيادة مدة المرض. ارتفع مستوى المؤشرات الحيوية حتى في الحالات المستقرة، وكان متوسط مستوى IL-6 (69.4 ± 35.29) بيكوغرام/مل ومتوسط TNF- α (72.3 ± 22.45) بيكوغرام/مل.

الإستنتاجات: يُظهر مرضى مرض الإنسداد الرئوي المزمن عبئاً مرضياً من حيث فقدان الإنتاجية في العمل وضعف النشاط الذي يزداد مع تقدم السن ومدة المرض. مرضى الإنسداد الرئوي المزمن الذين يعانون من انخفاض مؤشر كتلة الجسم هم أكثر عرضة لانخفاض وظائف الرئة ولأعراض أسوأ.

الكلمات المفتاحية: عبء المرض، مرض الإنسداد الرئوي المزمن، الإنتاجية، عامل نخر الورم- α ، الإنترلوكين-6.