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EFFECTS OF ADVERSE EVENTS ON THE HEALTH RELATED QUALITY OF LIFE OF COPD PATIENTS, A CROSS SECTIONAL STUDY IN TERTIARY CARE HOSPITALS OF LAHORE, PAKISTAN

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ABSTRACT

Objectives: Whether chronic obstructive pulmonary disease (COPD) standard treatment adverse effects had any impact on health related quality of life of COPD patients?

Method: A cross-sectional observational study conducted in six different tertiary care hospitals in Lahore over two months, from April to June 2025. The study included 385 indoor and outdoor patients with the age of 30 years and above either male or female, irrespective of their co-morbid conditions i.e., CVD, emphysema, asthma, hypertension. Patients with CKD, blood dyscrasias, immuno-compromised were excluded from this study. Data were collected through direct interview from the indoor and outdoor patients during their hospital visits by using structured and validated questionnaires. By using IMB SPSS Software descriptive statistics, chi-Square test and linear regression test were employed to analyze the collected data.

Result: This study showed that age (p = 0.001), smoking status (p = 0.001), COPD duration (p = 0.001) and treatment (p = 0.001) were associated with the severity of COPD. Similarly, the most common adverse effect of COPD medication was dry mouth (p = 0.001) occuring in 73.8% patients but had no significant correlation with daily functional areas. Muscle cramps was occurred in 52.5% of patients and had statistically significant correlations with mobility (p =

0.01), self-care (p = 0.004), pain (p = 0.002) and anxiety (p = 0.033). Tachycardia (30.6%) was most related to self-care (p = 0.017) and palpitations (15.3%) affected usual activities (p = 0.015). Urinary retention (12.5%) was related to higher anxiety (p = 0.012). Swelling (18.2%) and constipation (40.3%) had no significant impact on any of the health quality dimensions. The results of linear regression test showed that, three adverse effects urinary retention (p = 0.015), tachycardia (p = 0.018) and muscle cramps (p = 0.025) were associated with the standard treatment of COPD.

Conclusion: This study concludes that age, smoking and duration of COPD were associated with the severity of COPD. The most common adverse effect associated with COPD standard treatment such as: muscle cramp, tachycardia, palpitation and urinary retention had significant impact on patient's quality of life.

Introduction

Chronic obstructive pulmonary disease (COPD) was one of the leading causes of mortality and morbidity worldwide, affecting an estimated 4.18% people globally. [1] According to the world health organization (WHO), COPD is the fourth leading cause of morbidity and mortality worldwide. [2] In 2017, COPD caused 0.042% deaths, with over 90% of these according in low and middle income countries. According to the American Lung Association, COPD is twice as prevalent in rular areas due to barrier that complicate its diagnosis and treatment. [3]

Pakistan has a burden of 2.1% of COPD patients. [4] The prevalence of COPD increases due to increased smoking and aged population. [1] In Pakistan, both asthma and COPD are two major respiratory problems. [5] In 2018, the prevalence of COPD was 13.8% in EMR (Eastern Mediterranean Region) of Pakistan. According to a study conducted at the Aga Khan University Hospital Karachi, the prevalence of COPD is 5.7%. [6] The estimated prevalence of (COPD) in Pakistan is approximately 4%, contributing to 71 annual deaths per 100,000 population, as reported in the National Health Survey of Pakistan (NHSP) conducted between 1990 and 1994. [7]

COPD is the most common chronic respiratory disease that is associated with persistent airflow obstruction and inflammatory response to noxious particles and gases. [8] It interferes with normal breathing. [9] The leading cause of COPD is smoking. Other causes may include exposure to dust, chemicals, air pollution, respiratory infections and other lung diseases. [10] The pathogenesis of COPD is associated with immune inflammatory changes that are linked to a tissue-repair and remodeling process that enhances mucus production and causes emphysematous destruction of the gas-exchanging surface of the lung. [11] The sign and symptoms of COPD include cough, dyspnea, and airways limitation. [12]

The recommended therapy for COPD patients included smoking cessation, bronchodilators and inhaled corticosteroids. [13] Bronchodilators categorized into: beta-2 agonist, antimuscarinic and theophylline. Beta-2 agonist is classified into short-acting beta-2 agonists (salbutamol, albuterol, terbutaline, and levalbuterol) and long-acting beta-2 agonists (salmeterol, formoterol and vilanterol). [14] Anti-muscarinic drugs are also classified into short acting muscarinic antagonist (Ipratropium) and long-acting muscarinic antagonist (tiotropium, aclidinium, glycopyrrolate).

Theophylline is weak bronchodilator it relaxes airway smooth muscle leading to airflow and reduces symptoms of COPD. [15]

COPD medications were often associated with some adverse effects. Most of the patients treated with ICS (Inhaled corticosteroids) have adverse effect of pneumonia. Other adverse effects occur in patients treated with LABA (long-acting beta-2 agonist) are tremors, palpitation, muscle cramps and tachycardia. [8] Long-acting muscarinic antagonists (LAMA) are also associated with adverse effect of dry mouth, urinary retention and constipation. [16]

COPD impairs the quality of life of patients by preventing them from carrying out daily activities and from socializing or enjoying their hobbies. Patients often express frustration because they cannot perform their usual daily activities. [17] Psychological symptoms such as anxiety and depression are also common among COPD patients. [18] COPD also leads to disability, which affects the patient's family. [9] Treatment of COPD also effect on the patients quality of life and considerably increase severity of disease. They show progressive impairment of normal physical activities and decline in lungs performance. Psychiatric issues are observed in these patients and that could worsen COPD condition. [19] The purpose of this study is to highlight the influence of adverse effects on the patients quality of life. Some studies, such as those by Decramer et al. (2013) [20] and Miravitlles et al. (2017) [21] , have highlighted the prevalence of ADRs in COPD treatment, they have not systematically evaluated their impact on quality of life domains such as physical functioning, mental health, and social engagement [30]. The last research was conducted in Pakistan seven years ago in Karachi, focusing on to determine HQOL of COPD patients but is did not address effects of ADR on COPD patients quality of life. [9] The findings of this study help physicians to improve COPD management and reduce ADR which will improve patient's quality of life. This study aims to cover research gap in Pakistan as despite the increase in the burden of COPD patients in Pakistan, there has been no research conducted in Punjab on the effect of ADR on the COPD patients QOL.

Objectives:

To evaluate the impacts of adverse effects on health related quality of life in COPD patients undergoing COPD treatments.

Methodology

Study design

An observational, cross-sectional study design was conducted to evaluate the impact of adverse effect on health quality of COPD patients.

Study duration

The study was conducted for two months, from April to June 2025.

Study setting

This study was conducted in six different tertiary care hospitals in Lahore. These hospitals are providing specialized medical care and equipped with advanced medical and diagnostic tools. These hospitals are dealing with large number of patients in Punjab on daily basis.

Sample size

The sample size was calculated by using the Rao soft sample size calculator, [22] with 5% margin of error, 95% confidence level, Lahore population size 15 million, [23] and 50% response distribution, which resulted in a sample size of 385. Data were collected through direct interview from the patients by using structured and validated questionnaires [30].

Inclusion Criteria

Patients diagnosed with COPD either male/female of age 30 years and above, irrespective of their co-morbid conditions e.g., CVD, emphysema, asthma, hypertension were included in this study.

Exclusion criteria

Patients with cognitive impairment or a history of lung malignancies and lung fibrosis will be excluded from this study. Patients with co-morbidities e.g., CKD, blood dyscrasias, immuno-compromised patients will also be excluded from this study.

Data collection tool

The data collection tool contains four sections: i-Patient Consent form, ii- Patients Demographics: This section contains personal background characteristics, including socio-demographics variables (e.g., age, nationality, gender, marital status, education, employment, monthly income, exercise, smoking status, patient visit hospital for exacerbations last year, COPD type, COPD with emphesyma, cardiovascular disease, hypertension and COPD maintenance treatment, iii- COPD Assessment Test (CAT): The COPD Assessment Test (CAT) is a structured and validated questionnaire designed to measure the impact of COPD on a patient's daily life and overall health. [24] It consists of eight questions assessing symptoms such as cough, mucus production, chest tightness, breathlessness, and the effect of COPD on sleep and daily activities. [25] Each question is scored from 0 to 5, with the total CAT score ranging from 0 to 40. A higher score indicates a greater disease burden. CAT scores of 1-10, 11-20, 21-30 and 31-40 indicates categories of mild, moderate, severe and very severe health status, respectively. [26], iv- EuroQol 5 Dimension 5 Level (EQ-5D-5L): The EQ-5D-5L is a structured and validated questionnaire used to assess health-related quality of life. [27] The first part of EQ-5D-5L include five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. [28] Utility scores of each dimension ranging from 0 to 1, indicating no problem to extreme problems. The responses generate a health profile that can be converted into an index score using a value set specific to a population. The second part contains a visual analogue scale (VAS) allows individuals to rate their overall health from 0 (worst) to 100 (best).

Ethical Permission

The permission of study was approved by the Research and Ethics Committee (REC) and Board of Study (BOS) with reference number REC/GDIP/25/D-CP-26. Ethical permission has been obtained for the use of the EQ-5D-5L questionnaire in this study. Additionally, the COPD assessment tool is available for open-access use, allowing researchers to utilize it freely for evaluating disease impact.

Statistical analysis

The data will be analyzed using Statistical Package for the Social Sciences (SPSS), also known as IBM SPSS Statistics, version 27.0. Software to ensure accurate interpretation.

For univariate analysis: Descriptive statistics, such as percentages, arithmetic means with standard deviations will be conducted to describe patient’s demographics and clinical characteristics. For bivariate analysis: Chi-square test will be used to assess relationships between patients demographics and clinical characteristics and COPD. For multivariate analysis:

Multivariable Linear Regression will be conducted to determine effect of independent variables with significant correlations to each dependent variable.

Result:

The data in Table 1 was analyzed by using the SPSS. The analysis included univariate statistics (mean, median and frequency), and chi-square test was used to determine association between clinico-socio-demographics and COPD, and association between impact of adverse effects on the patients quality of life.

Table 1: Clinico-socio-demographics characteristics and their association with COPD

Demographic Characteristics	Mean (N)	Average (SD)	P-Value
Age 30 to 60 Above 60	235 150	1.390 (±0.483)	<0.001
Nationality Pakistani Other	378 7	1.018 (±0.133)	0.313
Gender Male Female	264 121	1.314 (±0.465)	<0.044
Marital Status Married Unmarried	356 29	1.075 (±0.264)	0.597
Education Matric Inter Graduation Post Graduation None	93 (24.2) 34 (8.8) 26 (6.8) 6 (1.6) 226 (58.7)	3.168 (±1.744)	<0.001
Employment Employed Un-employed Retired	136 (35.3) 218 (56.6) 31 (8.1)	1.727 (±0.600)	0.725
Monthly income Less Than 20,000 20,000 to 50,000 50,000 to 100,000 More Than 100,000	251 (65.2) 114 (29.6) 19 (4.9) 1 (0.3)	1.402 (±0.596)	<0.001
Exercise Yes No	42 (10.9) 343 (89.1)	1.890 (±0.312)	0.005
Smoking Status Smoker Non-smoker Ex-smoker	84 (21.8) 169 (43.9) 132 (34.3)	2.123 (±0.739)	<0.001
Exacerbation last year Yes	102 (26.5)	1.735 (±0.441)	<0.001

No	283 (73.5)		
Hypertension Yes No	 161 (43.4) 218 (56.6)	 1.566 (±0.496)	 0.207
Emphysema Yes No	 54 (14.0) 331 (86.0)	 1.859 (±0.347)	 0.207

Demographic Characteristics	Mean (N)	Average (SD)	P-Value
CVD[1] Yes No	 69 (17.9) 316 (82.1)	 1.820 (±0.384)	 0.834
COPD[2] **Duration**		870.88 (±1037.9)	<0.001
Treatment ATC[3] CS[4] +LABA[5] ATC+CS+LABA	 30 (7.8) 244 (63.4) 111 (28.8)	 2.210 (±0.868)	 <0.001
CAT Score[6] Never Mild Moderate Sever Very Severe	 0 (0) 9 (2.3) 101 (26.2) 199 (51.7) 76 (19.7)	 25.070 (±8.019)	 <0.001

[1]CVD, cardiovascular disease; [2]COPD, chronic obstructive pulmonary disease; [3]ATC, anticholinergics; [4]CS, corticosteroids; [5]LABA, long-acting beta agonist; [6]CAT, COPD assessment test. (Data were presented as mean (%) unless otherwise indicated. Chi-square test with level of significance 0.05 was conducted to check association between clinico-socio-demographics and COPD.)

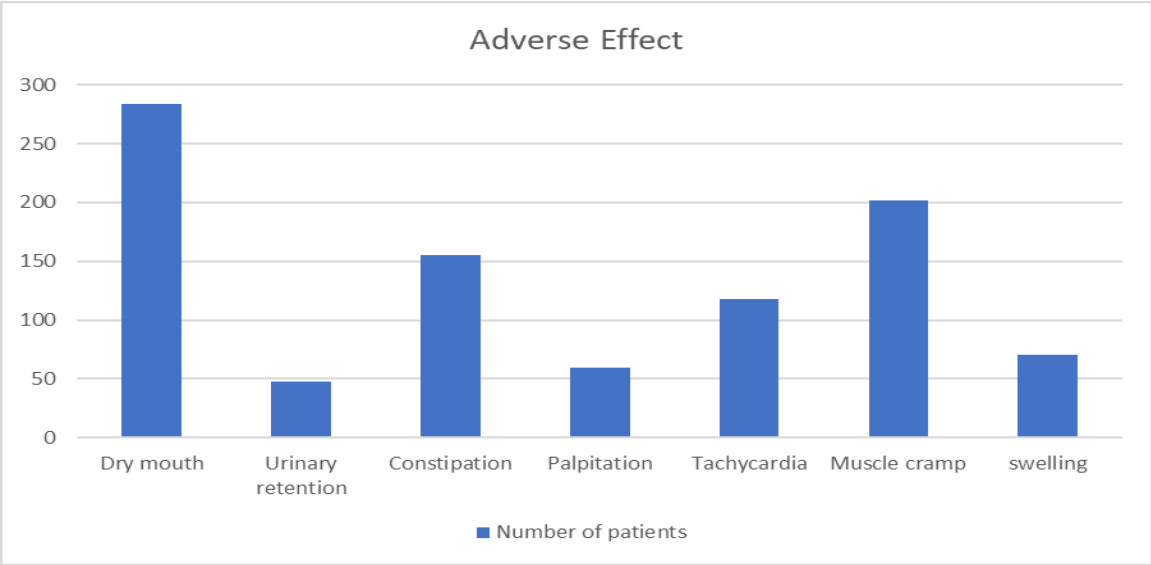
The given Table 2 showed the most common adverse effect of COPD medication dry mouth, occurring in 73.8% of patients, but having no significant correlation with daily functional areas. Muscle cramps occurred in 52.5% of patients and had statistically significant correlations with mobility ($p = 0.01$), self-care ($p = 0.004$), pain ($p = 0.002$), and anxiety ($p = 0.033$). Constipation was also prevalent (40.3%) but did not have a significant impact on daily functioning. Tachycardia (30.6%) was most related to self-care ($p = 0.017$), and palpitations (15.3%) affected usual activities ($p = 0.015$). Urinary retention (12.5%) was related to higher anxiety ($p = 0.012$). Swelling (18.2%) also not have a significant impact on any of the health quality domains. On the whole, muscle cramps proved to be the most significant adverse effect on quality of life.

Table 2: Prevalence of adverse effects among study participants and their association with health related quality of life.

Adverse Effect	Mean (%) Average (SD)	Mobility P-Value	Self Care P-Value	Usual Activities P-Value	Pain P-Value	Anxiety P-Value
Dry mouth	284 (73.8) 1.26 (±0.44)	0.347	0.083	0.87	0.947	0.747
Urinary retention	48 (12.5) 1.84 (±0.33)	0.753	0.407	0.064	0.707	0.012
Constipation	155 (40.3) 1.59 (±0.49)	0.127	0.069	0.702	0.159	0.146
Palpitation	59 (15.3) 1.84 (±0.36)	0.462	0.999	0.015	0.362	0.638
Tachycardia	118 (30.6) 1.69 (±0.47)	0.85	0.017	0.625	0.352	0.74
Muscle cramp	202 (52.5) 1.47 (±0.50)	0.01	0.004	0.05	0.002	0.033
Swelling	70 (18.2) 1.82 (±0.37)	0.218	0.779	0.448	0.533	0.315

(Data were presented as mean (%). Chi-square test eith level of significance 0.05 was conducted to determine association between adverse effects and utility score.)

The graph 1 showed that prevalence of dry mouth was found to be 73.8%, urinary retention 12.5%, constipation 40.3%, palpitation 15.3%, tachycardia 30.6%, muscle cramp 52.5%, swelling 18.2%.



Graph 1: Prevalence of adverse effects in COPD patients

The data mentioned in table 3 showed that 6.8% patients have no problem in mobility, similarly 11.4% patients have no problem in self care, 6.8% patients face no problem in usual activities, 15.8% patients have no pain and 28.8% patients have no anxiety. Meanwhile, 26.5% patient with mild problem in mobility, 32.7% with mild problem in self care, 31.4% with mild problem in usual activities, 33.8% with mild pain and anxiety.
Patients with moderate problems in mobility were 34%, self care 37.9%, usual activities 39.2%, pain 27.3% and anxiety 23.9%. Similarly, patients with severe problem in mobility were found to be 29.6%, self care 14.3%, urinary retention 19.5%, pain 18.7% and anxiety 11.2%. 3.1% patients have unable mobility, 3.6% patients were unable to do self care, 3.1% patients were unable to do their usual activities, 14.4% patients have very severe pain and 2.3% patients suffering from severe anxiety.

Table 3: Evaluation of utility score[1] in COPD patients

Utility score	Mobility Mean (N) (%)	Self care Mean (N) (%)	Usual activities Mean (N) (%)	Pain Mean (N) (%)	Anxiety Mean (N) (%)
No problem	26 (6.8)	44 (11.4)	26 (6.8)	61 (15.8)	111 (28.8)
Slight problem	102 (26.5)	126 (32.7)	121 (31.4)	130 (33.8)	130 (33.8)
Moderate problem	131 (34.0)	46 (37.9)	151 (39.2)	105 (27.3)	92 (23.9)
Severe problem	114 (29.6)	55 (14.3)	75 (19.5)	72 (18.7)	43 (11.2)
Unable	12 (3.1)	14 (3.6)	12 (3.1)	17 (14.4)	9 (2.3)

[1]EQ-5D-5L Questionnaire covers five dimensions of health: mobility, self care, usual activities, pain and anxiety.

Data were presented as mean (%) Three adverse reactions demonstrated statistically significant negative associations: urinary retention showed a coefficient of -0.123 ($p = 0.015$), tachycardia had a coefficient of 0.121 ($p = 0.018$), and muscle cramps displayed a coefficient of -0.115 ($p = 0.025$). These results suggest that these particular adverse effects may affect patients quality of life. Constipation revealed a marginally significant positive association coefficient 0.09 ($p = 0.049$), implying a potential but uncertain relationship with outcome measures as shown in table 4.

Table 4: Association between adverse effects and COPD standard treatment[1]

Predictors	Coefficient	95% Confidence Interval	P-value
Dry mouth	-0.003	-0.080 to 0.076	0.96
Urinary retention	-0.123	-0.130 to -0.014	0.015
Constipation	0.09	-0.09 to 0.164	0.049
Palpitation	0.018	-0.052 to 0.075	0.725
Tachycardia	-0.121	-0.179 to 0.017	0.018
Muscle cramp	-0.115	-0.189 to -0.013	0.025
Swelling	-0.039	-0.095 to 0.042	0.447

[1]COPD standard treatment: ATC, CS+LABA, ATC+CS+LABA.
Coefficients were estimated by using linear regression.

.The table 5 showed that age and smoking both had a significant negative impact on HRQoL, with p-values of 0.026 and 0.017, respectively. Meanwhile, hypertension (p = 0.025) and asthma (p = 0.004) were also found to be significant contributors, indicating that comorbid conditions may exacerbate the burden of COPD. Muscle cramps (p = 0.030) and swelling (p = 0.014) were strongly associated with lower HRQoL.

Table 5: Predictors of HRQoL[1] in COPD patients

Predictors	Coefficients	95% Confidence Interval	P-value
Age	-0.118	-5.952 to -0.384	0.026
Smoking	0.120	0.389 to 3.888	0.017
Last year	-0.001	-3.025 to 2.936	0.976
Hypertension	-0.120	-5.940 to -0.405	0.025
COPD[3] type	-0.129	-5.304 to 0.706	0.133
Emphysema	-0.072	-6.441 to 0.973	0.148
CVD[2]	0.076	-0.953 to 6.151	0.151
Asthma	-0.147	-6.592 to -1.295	0.004
Treatment	-0.065	-3.859 to 0.858	0.212
Severe disease	0.066	-2.838 to 6.621	0.432
Dry mouth	0.098	-0.087 to 5.926	0.057
Urinary retention	0.020	-3.234 to 4.802	0.702
Constipation	0.017	-2.289 to 3.173	0.750
Palpitations	-0.038	-5.065 to 2.285	0.458
Tachycardia	0.040	-1.760 to 4.063	0.437
Muscle cramp	-0.112	-5.600 to -0.290	0.030
Swelling	-0.129	-7.913 to -0.890	0.014

[1]HRQoL, Health related quality of life; [2]CVD, cardiovascular disease; [3]COPD, chronic obstructive pulmonary disease. Coefficients were estimated by using linear regression statistically significant at the 0.05

DISCUSSION

This research was a cross-sectional observational study conducted in different tertiary care hospitals in Lahore over two months, from April to June. The study included 385 indoor and outdoor patients with the age of 30 years and above either male or female, irrespective of their co-morbid conditions i.e., CVD, emphysema, asthma, hypertension in this study. Patients with CKD, blood dyscrasias, immuno-compromised was excluded from this study.

The data collection tool was divided into four sections: A- Patient Consent form, B- Patient Demographics, C- COPD Assessment Test (CAT), D- EuroQol 5 Dimension 5 Level (EQ-5D-5L). [28] EQ-5D-5L Questionnaire covers five dimensions of health: mobility, self-care, usual activities, pain and anxiety. By using IMB SPSS Software descriptive statistics [22], chi-Square test and linear regression test were employed to analyze the collected data.

The most frequent adverse effect was dry mouth, affected 73.8% of the patients experienced. Even though it was prevalent, but it had no statistically significant correlation with any of the five domains, possibly making it an uncomfortable but tolerable problem for the majority of patients. On the other hand, muscle cramps, experienced by 52.5% of participants, had a strong adverse effect in four domains: mobility, self-care, pain, and anxiety. This indicates muscle cramps as one of the most impairing adverse effects, most likely to impact physical functioning and emotional well-being.

Adverse effects related to the cardiovascular system were also observed: tachycardia was significantly correlated with self-care difficulty ($p = 0.017$), and palpitations were associated with impairment in the performance of daily activities ($p = 0.015$). These symptoms can cause physical discomfort or fear of activity, thereby constraining daily independence. Also, urinary retention, although it occurred in a lesser proportion (12.5%), had a direct correlation with heightened levels of anxiety, which may be because of pain or further complications. Swelling in 18.2% of patients and constipation in 40.3% of patients, was not significantly related to any domain of quality of life.

This study identified several adverse effects from the standard COPD treatments: anticholinergic drugs often cause bladder issues and increased heart rate, while bronchodilators may trigger muscle cramps by altering electrolyte balance. Linear regression test showed that urinary retention ($p = 0.015$), constipation ($p = 0.049$), tachycardia ($p = 0.018$) and muscle cramp ($p = 0.025$) has statistically significant correlation with the COPD standard treatment.

Muscle cramps (a key finding in this research) and confusion [29] were identified as the most serious ADRs, significantly impairing mobility, self-care, and emotional well-being. Cardiovascular symptoms such as tachycardia and palpitations though less commonly discussed in the literature, were found in this study and Rodrigue et al. (2016) [8] to notably disrupt daily functioning. Additionally, urinary retention particularly linked to anticholinergic effects, contribute to anxiety and reduced HRQoL.

Furthermore, predictors of HRQoL showed that age, smoking, hypertension, asthma, dry mouth, muscle cramp and swelling negatively impact the patients quality of life. Real-world data, as highlighted by Rodrigue et al., [8] reveal that ADRs are more prevalent in clinical practice than in controlled trials, underscoring the need for ongoing monitoring. Collectively, these findings highlight the importance of individualized COPD management, where proactive identification and mitigation of high-impact ADRs can improve patient outcomes and overall quality of life

Future research with larger patient groups should investigate these medication effects more thoroughly, particularly the unexpected association with muscle cramps. For now, healthcare providers should remain especially vigilant for urinary, cardiac, and muscular side effects when

managing COPD patients, as these may be important indicators of treatment effectiveness and patient tolerance.

Conclusion:

This study highlighted that certain adverse effects particularly muscle cramps (p = 0.025), urinary retention (p = 0.015), tachycardia (p = 0.018) require closer attention due to their noticeable influence on physical functioning and emotional health.

Dry mouth and constipation, though common, appeared to be more manageable and less disruptive in terms of quality of life. However, this doesn't diminish their importance in individual cases. These findings emphasized the need for personalized care, where healthcare providers closely monitor and address the adverse effects experienced by each patient. Adjusting treatment plans to minimize these issues could lead to improved quality of life and better treatment adherence.

Certain predictors of HRQoL such as age (p = 0.026), smoking (p = 0.017), hypertension (p = 0.025), asthma (p = 0.004) also had negative impact on patients quality of life. Ultimately, while medications remain essential in managing COPD, attention must be given to their adverse effects, especially those medications that affecting mobility, self-care, and mental health can greatly enhance patient outcomes.

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