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Effectiveness of inhaled corticosteroids on COPD exacerbation rates based on serum eosinophil count; a prospective cohort study

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Abstract

Introduction: Chronic obstructive pulmonary disease (COPD) is a heterogeneous respiratory condition characterized by chronic inflammation and exacerbations. Inhaled corticosteroids (ICS) are commonly prescribed to reduce exacerbation risk, yet their efficacy varies among patients. Emerging evidence suggests that blood eosinophil count may serve as a biomarker to predict ICS responsiveness in COPD patients.

Objectives: This study investigates the relationship between serum eosinophil counts and the effectiveness of ICS in reducing COPD exacerbation rates.

Patients and Methods: This prospective cohort study enrolled 430 COPD patients from two major pulmonology centers in Tehran, Iran, between May 2021 and November 2022. After obtaining written informed consent, demographic data and spirometry measurements were collected to classify COPD severity according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria. Venous blood samples were analyzed for eosinophil counts, categorizing patients into groups with counts below or above 300 cells/μL. Participants were followed for six months to record clinical outcomes, including mortality, hospitalizations, and outpatient visits related to COPD exacerbations. The study's primary focus was to assess the impact of ICS on exacerbation rates stratified by eosinophil levels, aiming to evaluate eosinophil count as a biomarker for treatment responsiveness and to inform personalized COPD management.

Results: In a population of COPD patients who underwent ICS, the results indicated that patients with eosinophil counts higher than 300 cells/μL, compared to those with lower counts, demonstrated significantly fewer hospitalization rates (unadjusted B: -0.52 and adjusted B: -0.55). Similarly, the relationship between elevated eosinophil counts and outpatient visit frequency showed significant negative associations (unadjusted B: -1.82 and adjusted B: 1.88). However, in terms of six-month outcomes (recovery versus death), no statistically significant differences were observed between the two groups.

Conclusion: These findings suggest that blood eosinophil counts ≥300 cells/μL are associated with a pronounced reduction in severe COPD exacerbations among patients treated with ICS. This supports the use of eosinophil levels as a practical biomarker to guide ICS therapy, enabling more targeted, personalized treatment strategies that optimize clinical outcomes in COPD management.

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Introduction

Chronic obstructive pulmonary disease (COPD) exacerbations represent acute worsening of respiratory symptoms that accelerate lung function decline, increase mortality risk, and impose substantial healthcare burdens (1,2). These events exhibit heterogeneous triggers ranging from viral infections to environmental pollutants, with variable clinical presentations complicating standardized definitions (2,3). Current diagnostic criteria combine symptom-based assessments with healthcare utilization metrics, yet this approach lacks precision in identifying patients most likely to benefit from specific therapies (2,4). The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines emphasize exacerbation prevention as a key treatment target, necessitating biomarkers to optimize therapeutic strategies (5,6).

Inhaled corticosteroids (ICS) remain

Key point

In our prospective cohort study of chronic obstructive pulmonary disease (COPD) patients receiving inhaled corticosteroids (ICS), we observed that individuals with peripheral blood eosinophil counts greater than 300 cells/μL experienced less severe COPD exacerbations compared to those with lower eosinophil counts.

controversial in COPD management due to their variable efficacy and well-documented risks of pneumonia (5,7). While ICS/long-acting bronchodilator combinations reduce exacerbation frequency in select populations, indiscriminate use exposes many patients to adverse effects without clinical benefit (6,7). This therapeutic paradox has driven research into predictive biomarkers, with blood eosinophil counts emerging as the most promising candidate for personalizing ICS therapy (5,6,8). Mechanistically, eosinophils reflect type 2 airway inflammation responsive to corticosteroid modulation, though their predictive value appears threshold-dependent and influenced by comorbidities (5,8).

Recent evidence suggests serum eosinophil levels may stratify ICS responsiveness, with thresholds ≥300 cells/μL consistently associated with greater exacerbation reduction (5,6,8). However, conflicting data indicate elevated eosinophils might paradoxically predict higher baseline exacerbation risk, creating clinical uncertainty about their role in treatment algorithms (8). This dichotomy underscores the need for rigorous evaluation of eosinophil-guided ICS strategies, particularly given evolving definitions of COPD exacerbations and growing recognition of phenotype-specific therapeutic responses (3,4). The current study investigates these relationships through a systematic analysis of eosinophil thresholds and ICS efficacy across diverse.

Objectives

The objective of this prospective cohort study is to evaluate the effectiveness of ICS in reducing the rate of COPD exacerbations, with a particular focus on how this effect varies according to patients' serum eosinophil counts. Specifically, the study aims to determine whether patients with higher blood eosinophil levels (≥300 cells/μL) experience a differential benefit from ICS therapy compared to those with lower eosinophil counts, by analyzing exacerbation rates, hospitalizations, outpatient visits, and outcomes (recovery or death) over the follow-up period. By stratifying outcomes based on eosinophil thresholds, this research seeks to clarify the utility of blood eosinophil count as a predictive biomarker for ICS responsiveness and to inform more personalized treatment strategies for COPD management.

Patients and Methods

Study design and participants

This longitudinal, prospective cohort study was conducted on 430 patients diagnosed with COPD who were referred to two major pulmonology centers in Tehran, Iran, Imam Hossein and Masih Daneshvari hospitals-over 18 months spanning from May 2021 to November 2022.

Inclusion and exclusion criteria

The inclusion criteria encompassed patients with confirmed COPD classified as GOLD categories C and D (9,10), who provided written informed consent to participate in the study. Eligible participants were adults over 18 years of age with forced expiratory volume in one second (FEV1) values below 50% of predicted, who were initiating ICS (Symbicort spray) for the first time and continued during a six-month follow-up. The study protocol excluded patients with incomplete documentation during the six-month follow-up period, as well as those who died from causes unrelated to COPD complications.

Definition of COPD exacerbation

The COPD exacerbation is defined as an acute worsening of respiratory symptoms necessitating additional medical intervention (11,12). In this study, to operationalize this definition, we assessed exacerbations based on the frequency of hospitalizations and outpatient visits attributable to COPD, as well as patient outcomes, specifically, recovery or death, over a six-month follow-up period.

Data collection

At the start of the study, written informed consent was obtained from all participants. Demographic information, including age and gender, was collected through participant interviews. Each participant underwent spirometry testing to determine their FEV1 values, and COPD severity was classified as either class C or class D based on GOLD criteria. Venous blood samples were drawn and analyzed for complete blood count (CBC) and eosinophil levels, with patients subsequently grouped according to whether their eosinophil count was below or above 300 cells/μL. Participants were then followed for six months, during which key outcomes, including mortality rates, number of hospitalizations, and outpatient visits-were recorded. These outcomes were compared between the two eosinophil-level groups to assess potential differences related to eosinophil counts.

Outcomes

The primary outcome of this prospective cohort study is assessing outcomes, including the number of hospitalizations and outpatient visits attributable to COPD exacerbations, as well as patient outcomes measured by mortality and recovery rates during the follow-up period. Secondary outcomes are the rate of COPD exacerbations over a six-month follow-up period, stratified by patients' serum eosinophil counts (≥300 cells/μL versus <300 cells/μL), to evaluate the effectiveness of ICS in reducing

exacerbation frequency. These outcomes collectively assess the clinical impact of ICS therapy concerning eosinophil levels, aiming to clarify the predictive value of blood eosinophil count for treatment responsiveness and to inform personalized COPD management strategies.

Statistical analysis

Statistical analyses were conducted using IBM SPSS Statistics version 27 (IBM Corp., USA). The normality of quantitative variables was assessed with the Kolmogorov-Smirnov test. Group comparisons for continuous variables were performed using independent t-tests, while categorical variables were analyzed using chi-square tests. To evaluate the association between the eosinophil count threshold of 300 cells/μL and COPD exacerbations, both univariate and multivariate linear logistic regression models were employed.

Results

The study population included 430 COPD patients (259 males and 171 females), with a mean age of 59.79 ± 17.98 years. A higher proportion of patients were classified as COPD class D than class C according to the GOLD criteria. Following the six-month observation period, the vast majority of patients demonstrated recovery, while a small fraction experienced mortality. Notably, the distribution of peripheral blood eosinophil counts showed that approximately three-quarters of the participants exhibited counts exceeding 300 cells/μL, with the remainder falling below this threshold. The number of hospitalizations was 2.44 ± 1.95 times, and the number of outpatient visits was 10.29 ± 6.91 times (Table 1).

Table 1. Baseline characteristics of all participating patients

Variables	N	Percent
Gender		
Male	259	60.2
Female	171	39.8
COPD classification		
Class C	191	44.4
Class D	239	55.6
Outcomes after 6 months of follow-up		
Recovery	406	94.4
Death	24	5.6
Eosinophil count (cells/μL)		
<300	116	27
>300	314	73
Quantitative variable	**Mean**	**SD**
Age (year)	59.79	17.98
FEV1 (%)	34.10	9.24
Number of hospitalizations	2.44	1.95
Number of outpatient visits	10.29	6.91

N: Number; SD: Standard deviation; COPD: Chronic obstructive pulmonary disease; FEV1: Forced expiratory volume in 1 second.

The frequency distribution analysis of demographic and clinical characteristics between two groups of COPD patients stratified by peripheral blood eosinophil count, lower and higher than 300 cells/μL, revealed several noteworthy patterns. When examining gender distribution, COPD classification (class C versus class D), and six-month outcomes (recovery versus death), no statistically significant differences were observed between the two groups. Similarly, age and forced expiratory volume in one second (FEV1) showed comparable distributions across both eosinophil groups without reaching statistical significance. However, healthcare utilization metrics, which were considered as the criteria for COPD exacerbation, demonstrated significant differences between the groups, with patients having higher eosinophil counts (>300 cells/μL) experiencing significantly lower hospitalizations and outpatient visits compared to those with lower eosinophil counts (<300 cells/μL) (Table 2).

The linear logistic regression analysis examining the relationship between peripheral blood eosinophil counts and COPD exacerbations revealed significant negative correlations between eosinophil counts and COPD exacerbations. Using patients with eosinophil counts below 300 cells/μL as the reference group, those with elevated counts demonstrated significantly fewer hospitalizations, as evidenced by negative B coefficients in both unadjusted (B = -0.52) and adjusted (B = -0.55) models. Similarly, the relationship between elevated eosinophil counts and outpatient visit frequency showed significant negative associations in both unadjusted (B = -1.82) and adjusted (B = -1.88) analyses. These findings suggest that patients with eosinophil counts exceeding 300 cells/μL experienced fewer COPD-related healthcare encounters compared to those with lower counts, potentially indicating a lower severity of COPD exacerbation in these patients (Table 3).

Discussion

In this study, we studied COPD patients using ICS and found that those with higher eosinophil levels in their blood (above 300 cells/μL) had less severe COPD flare-ups than those with lower eosinophil levels. Our finding that COPD patients with higher blood eosinophil levels (above 300 cells/μL) experienced fewer severe exacerbations when using ICS aligns with multiple studies in the current literature. This relationship between elevated eosinophil counts and improved ICS response represents an important area for precision medicine in COPD management. Our result is consistent with multiple systematic reviews and clinical trials. A 2020 systematic review and meta-analysis by Harries et al demonstrated that ICS therapy provides greater benefit in preventing COPD exacerbations as blood eosinophil counts increase (13). Similarly, Oshagbemi et al in a systematic review and meta-analysis study found

Table 2. Frequency distribution of demographic and clinical characteristics of COPD patients stratified by peripheral blood eosinophil count threshold (300 cells/μL)

Variable	Sub-variable	Eosinophil count (cells/μL)				*P* value
		< 300 (N = 116)		> 300 (N = 314)		
		N	%	N	%	
Gender	Male (n = 259)	73	28.2	186	71.8	0.487*
	Female (n = 171)	43	25.1	128	74.9	
COPD classification	Class C (n = 191)	47	24.6	144	75.4	0.322*
	Class D (n = 239)	69	28.9	170	71.1	
Outcomes after 6 months of follow-up	Recovery (n = 406)	112	27.6	294	72.4	0.242*
	Death (n = 24)	4	16.7	20	83.3	
Variable		**Mean**	**SD**	**Mean**	**SD**	***P* value**
Age (year)		61.01	17.04	59.34	18.32	0.393**
FEV1 (%)		34.78	7.36	33.85	9.85	0.293**
Number of hospitalizations		2.82	2.17	2.30	1.85	0.023**
Number of outpatient visits		11.62	7.67	9.80	6.55	0.024**

N: Number; SD: standard deviation; COPD: Chronic obstructive pulmonary disease; FEV1: Forced expiratory volume in 1 second.
*Chi-square; **Independent T-test.

Table 3. The correlation between the eosinophil count threshold at 300 cells/μL and COPD exacerbations using univariate and multivariate linear logistic regression

Variable		Number of hospitalizations							
		Unadjusted				Adjusted			
		P-value	B	95% CI		*P* value	B	95% CI	
				Lower	Upper			Lower	Upper
Eosinophil count (cells/μL)	<300	Reference (1)							
	>300	0.014	- 0.52	- 0.93	- 0.10	0.007	- 0.55	- 0.96	- 0.15
Variable		**Number of outpatient visits**							
		Unadjusted				**Adjusted**			
		***P* value**	**B**	**95% CI**		***P* value**	**B**	**95% CI**	
				Lower	**Upper**			**Lower**	**Upper**
Eosinophil count (cells/μL)	<300	Reference (1)							
	>300	0.015	- 1.82	- 3.28	- 0.35	0.012	- 1.88	- 3.34	- 0.42

B, Unstandardized coefficients; CI, Confidence interval.

a significant reduction in the risk of moderate or severe exacerbations in patients with absolute blood eosinophil thresholds ranging from ≥100 to ≥340 cells/μL who escalated to ICS therapy. The threshold of 300 cells/μL appears particularly significant, as their analysis showed that de-escalation of ICS in patients with counts ≥300 to ≥340 cells/μL resulted in an increased risk of exacerbations (6). Post-hoc analysis of a study by Bafadhel et al, further supports our findings, showing that budesonide/glycopyrronium/formoterol fumarate dihydrate (BGF) triple therapy reduced moderate/severe exacerbation rates compared to dual therapy without ICS, with treatment differences increasing as eosinophil counts rose (14). This dose-response relationship between eosinophil counts and ICS effectiveness provides additional validation for our results.

In contrast with our study, Chen and colleagues' meta-analysis presents an interesting counterpoint, suggesting that high blood eosinophils (≥300 cells/μL) are associated with an increased risk of COPD exacerbation (8). This apparent contradiction may indicate that while patients with higher eosinophil counts are at greater baseline risk for exacerbations, they also derive greater benefit from ICS therapy. Indeed, Cheng et al meta-analysis study demonstrated a 17% reduction in exacerbations among patients with ≥2% blood eosinophils who received ICS therapy compared to control groups (5).

In comparison of the exacerbation history with the eosinophil count as a predictor of future COPD exacerbations, some research suggests exacerbation history may be more predictive than blood eosinophils alone. Worth et al found that in real-world COPD patients, exacerbation history was a more reliable predictor of future exacerbations than eosinophil counts (15). The study by Calverley et al indicated that withdrawal of ICS only increased exacerbation rates in patients with both raised eosinophils (≥400 cells/μL) and a history of frequent exacerbations (16). These findings suggest that optimal treatment decisions might require considering both biomarkers and clinical history.

Overall, our finding that COPD patients with blood eosinophil counts above 300 cells/μL experience fewer exacerbations when using ICS aligns with the growing consensus that eosinophil counts can help identify patients most likely to benefit from ICS therapy. The research demonstrates a relationship between higher eosinophil counts and greater ICS efficacy for exacerbation prevention, though the interplay with exacerbation history merits consideration in clinical decision-making. This personalized approach to COPD management may help optimize treatment outcomes while minimizing unnecessary ICS exposure in patients unlikely to benefit.

Conclusion

This prospective cohort study provides compelling evidence that blood eosinophil count may serve as a valuable biomarker for predicting response to ICS therapy in COPD patients. Our findings demonstrate that patients with peripheral blood eosinophil counts exceeding 300 cells/μL who received ICS therapy experienced significantly fewer severe COPD exacerbations compared to those with lower eosinophil counts. These findings suggest that blood eosinophil count could guide more targeted therapeutic approaches, with clinicians potentially prioritizing ICS therapy in COPD patients with eosinophil counts above 300 cells/μL while exploring alternative treatment strategies for those with lower counts. Future research should focus on validating these findings in larger, more diverse populations and investigating the underlying mechanisms by which elevated eosinophil counts may predict enhanced ICS responsiveness.

Limitations of the study

First, as a prospective cohort study conducted at only two hospitals in Tehran, the results may have limited generalizability to broader or more diverse populations. Second, the reliance on a single baseline measurement of eosinophil count may not fully capture fluctuations over time, potentially affecting the accuracy of patient classification. Third, potential confounding factors such as variations in adherence to ICS therapy, comorbidities, and environmental exposures were not fully controlled, which could influence exacerbation rates and outcomes. Additionally, the six-month follow-up period may be insufficient to observe long-term effects of treatment or disease progression.

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Authors' contribution

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Ethical issues

The research conducted in this study adhered to the principles outlined in the Declaration of Helsinki and was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences (Ethical code No: IR.SBMU.MSP.REC.1400.071; https://ethics.research.ac.ir/EthicsProposalView.php?id=196305). Prior to any intervention, all participants provided written informed consent. The study was extracted from Zeinab Taabzadeh internal medicine residency thesis at this university (Thesis #28418). The authors have fully complied with ethical issues, such as plagiarism, data fabrication, and double publication.

Declaration of generative artificial intelligence (AI) and AI-assisted technologies in the writing process

While preparing this work, the authors utilized AI (Perplexity.ai and Grammarly.com) to refine grammar points and language style in writing. Subsequently, the authors thoroughly reviewed and edited the content as necessary, assuming full responsibility for the publication's content.

Conflicts of interest

The authors declare that they have no competing interests.

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