

Association of FeNO Decline Rate with Symptom Improvement in COPD: A Real-World Observational Study

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Background: The association between relative changes in fractional exhaled nitric oxide (FeNO) in chronic obstructive pulmonary disease (COPD) with patient-reported symptoms improvements remains uncertain.

Objective: To assess the association of the rate of FeNO decline with the achievement of the minimum clinically important difference (MCID) in COPD Assessment Test (CAT) score.

Methods: We conducted a single-center, retrospective real-world study involving 111 adults with COPD. Patients were classified into two groups: those with symptom improvement (CAT decline ≥ 2 points) and those with no improvement (CAT decline < 2 points). Logistic regression evaluated associations between FeNO decline rate and CAT MCID, adjusting for clinically relevant covariates. Receiver operating characteristic (ROC) curve analysis estimated the discriminatory performances of it.

Results: Of 111 patients, 53 (47.7%) achieved the CAT MCID. Multivariate logistic regression found that the rate of FeNO decline was independently associated with symptom improvement (adjusted OR 2.08, 95% CI 1.01–4.29, $P=0.047$). Baseline CAT also showed association with symptom improvement (adjusted OR 1.06, 95% CI 1.00–1.12, $P=0.034$). BMI showed a positive trend but without statistical significance (adjusted OR 1.13, 95% CI 1.00–1.29, $P=0.056$). AUC of FeNO decline rate, baseline CAT, combined with BMI in discriminating CAT MCID were 0.713 (95% CI 0.617, 0.809).

Conclusion: The rate of FeNO decline was significantly associated with clinically meaningful CAT improvement in this study, which indicated dynamic measures of type-2 inflammation can complement blood eosinophil counts to refine phenotyping and inform precision management in COPD.

Keywords: COPD, the rate of FeNO declined, CAT MCID, type-2 inflammation, treatable traits, precision medicine

Introduction

Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide, characterized by persistent respiratory symptoms and progressive airflow limitation.^{1,2} Symptom burden is a major determinant of health-related quality of life and prognosis in COPD, and the COPD Assessment Test (CAT) is widely used as a reliable tool to quantify symptom severity and monitor clinical changes.³ A decline of 2 points in CAT score has been established as the minimum clinically important difference (MCID), representing a meaningful improvement in symptoms.⁴ Identifying discriminators of clinically significant CAT improvement is therefore of great importance, as it may help guide therapeutic decision-making and patient management.

Fractional exhaled nitric oxide (FeNO) is a noninvasive, reproducible marker of type-2 (T2) airway inflammation with well-established clinical utility in asthma.⁵ Its role in COPD, however, remains less clearly defined. Prior studies suggest that FeNO levels in COPD correlate with eosinophilic inflammation⁶ and may discriminate the response to inhaled corticosteroids

(ICS),⁷ as well as clinical outcomes such as exacerbation risk, lung function decline, and all-cause mortality.⁸ Nonetheless, evidence on the association between baseline FeNO levels and clinical outcomes has been inconsistent.^{9,10}

FeNO levels vary substantially among COPD patients and are influenced by factors such as current smoking status.¹¹ It remains uncertain whether changes in FeNO can reliably discriminate improvements in patient-reported outcomes. We hypothesized that the rate of FeNO decline following treatment may better reflect the suppression of airway inflammation and thus provide a more sensitive indicator of treatment responsiveness than baseline FeNO values.

The present study aimed to evaluate the discriminative value of FeNO dynamics for achieving the MCID in CAT score among patients with COPD in a real-world cohort.

Materials and Methods

Study Population

Data for this study were obtained from a single center (Beijing Chao-Yang Hospital) as part of the COMFORT study (ClinicalTrials.gov ID: NCT03044847; details available at chinacopd.com/#/hot), spanning December 2016 to January 2021. Both baseline and follow-up visit data were collected, with a median follow-up duration of 414 days (interquartile range: 366–721 days).

Participants were eligible for inclusion if they met the following criteria: (1) aged 40–75 years; (2) diagnosed with COPD, defined as a post-bronchodilator FEV₁/FVC ratio <0.70 according to the GOLD guidelines.¹² Exclusion criteria included acute exacerbation within the last month, comorbid asthma or tuberculosis, and a history of lung resection surgery for lung cancer. The study flow chart is presented in Figure 1.

Ethical approval for this research was obtained from the Ethics Committee of Beijing Chao-Yang Hospital (Approval No. 2016-KE-183). The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment.

Data Collection

The following data were collected: age, sex, body mass index (BMI), smoking history, comorbidities, medication use, history of severe exacerbations, COPD Assessment Test (CAT) score, lung function, fractional exhaled nitric oxide (FeNO), immunoglobulin E (IgE), and blood cell counts. FeNO was measured using a nitric oxide analyzer with electrochemical sensors (NIOX; Aerocrine AB, Stockholm, Sweden), according to the American Thoracic Society (ATS)/European Respiratory Society (ERS) guidelines.¹³ Patients performed repeated and reproducible exhalations at a constant flow rate of 50 mL/s to obtain at least two NO plateau values that agreed within 10% of each other. The FeNO decline rate was calculated using the formula: (baseline FeNO – follow-up FeNO)/baseline FeNO. Severe exacerbations were defined as acute events requiring hospitalization or an emergency room visit. Symptom improvement was defined as achieving the minimum clinically important difference (MCID) in CAT (a decline of ≥ 2 points).

Statistical Analysis

Continuous variables were reported as mean $\pm$ standard deviation (SD) or as median with interquartile range (IQR). Categorical variables were presented as counts and percentages. Comparisons between groups were performed using the Student's *t*-test or Mann–Whitney *U*-test for continuous variables, and the Chi-squared test for categorical variables. The association between FeNO decline rate and CAT MCID was assessed using logistic regression, with results presented as adjusted odds ratios (ORs) and 95% confidence intervals (CIs). Covariates included in the multivariate logistic regression were selected based on their clinical relevance and statistical significance in univariate analyses ($P < 0.1$). Receiver operating characteristic (ROC) curve analysis was conducted to assess the discriminable performances of factors in discriminating CAT MCID, as presented by areas under the ROC curve (AUCs). A two-sided *P*-value <0.05 was considered statistically significant. All statistical analyses were conducted using R software (version 4.4.1).

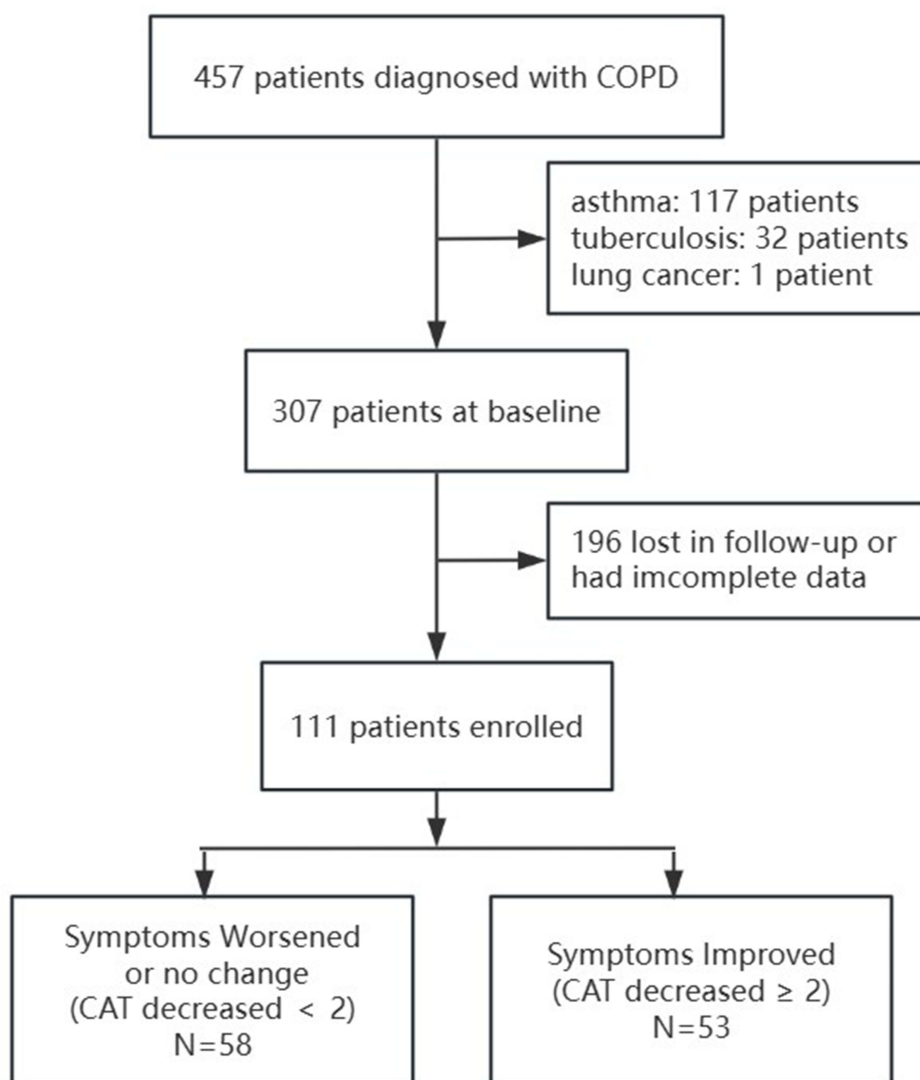


Figure 1 Flow chart.

Results

Baseline Characteristics

A total of 111 patients with COPD were included in this study. The median age was 65.5 years, and 95.5% of participants were male. According to Asian criteria, in which a body mass index (BMI) ≥ 24 kg/m² is considered overweight,¹⁴ the study population was generally slightly overweight. At baseline, 38.7% of patients were current smokers, and the majority were classified as GOLD stage II–III.

Participants were categorized into two groups according to whether they achieved MCID in CAT score (Table 1). Baseline CAT scores were significantly higher in the symptom improvement group compared with the non-improvement group (15.57 vs 11.59, $P = 0.008$). Patients in the symptom improvement group tended to have a higher BMI compared with those in the non-improvement group (25.07 vs 23.85 kg/m², $P = 0.052$). Baseline FeNO levels and absolute FeNO decline did not differ significantly between groups. However, the FeNO decline rate was significantly greater in the symptom improvement group than in the non-improvement group (19.0% vs 4.0%, $p = 0.039$).

Table 1 Baseline Characteristics. COPD Patients Were Categorized as Symptom Non-Improvement Group and Improvement Group

Variables	All N=111	Non-improvement N=58	Improvement N=53	P-value
Gender, male	106 (95.50%)	54 (93.10%)	52 (98.11%)	0.366
Age, year	65.46 (6.99)	65.07 (7.20)	65.89 (6.80)	0.540
BMI, kg/m ²	24.43 (3.31)	23.85 (3.19)	25.07 (3.36)	0.052
Current smoking	43 (38.74%)	20 (34.48%)	23 (43.40%)	0.182
Comorbidities				
Cardio-/cerebro- vascular disease	50 (45.05%)	27 (46.55%)	23 (43.40%)	0.886
Digestive system diseases	21 (19.09%)	12 (20.69%)	9 (17.31%)	0.836
Endocrine metabolic diseases	21 (18.92%)	13 (22.41%)	8 (15.09%)	0.459
Other diseases	34 (30.91%)	15 (26.32%)	19 (35.85%)	0.382
Severe exacerbation in last year	29 (26.13%)	15 (25.86%)	14 (26.42%)	1.000
Lung Function				
FVC pre-BD, L	2.85 (2.38,3.34)	2.83 (2.38,3.35)	2.87 (2.37,3.32)	0.788
FVC post-BD, L	3.09 (2.55,3.71)	3.06 (2.54,3.62)	3.10 (2.74,3.72)	0.797
FEV ₁ pre-BD, L	1.38 (1.08,1.95)	1.29 (1.07,1.96)	1.45 (1.11,1.94)	0.752
FEV ₁ post-BD, L	1.56 (1.17,2.20)	1.52 (1.13,2.21)	1.71 (1.18,2.17)	0.721
FEV ₁ %pred, pre-BD	52.03 (37.94,66.12)	51.20 (36.75,65.86)	53.29 (41.18,66.20)	0.399
FEV ₁ %pred, post-BD	60.82 (45.76,77.13)	56.15 (43.30,76.16)	64.29 (45.88,80.84)	0.363
FEV ₁ /FVC pre-BD	52.40 (42.43,61.00)	50.86 (42.22,63.15)	52.46 (43.84,59.50)	0.710
FEV ₁ /FVC post-BD	53.50 (43.99,62.50)	52.62 (43.14,64.13)	55.59 (44.85,60.55)	0.754
GOLD grades				0.732
1	26 (23.42%)	12 (20.69%)	14 (26.42%)	
2	44 (39.64%)	22 (37.93%)	22 (41.51%)	
3	38 (34.23%)	22 (37.93%)	16 (30.19%)	
4	3 (2.70%)	2 (3.45%)	1 (1.89%)	
Medication				0.382
Untreated	30 (27.27%)	14 (24.56%)	16 (30.19%)	
ICS + LABA	24 (21.82%)	13 (22.81%)	11 (20.75%)	
ICS + LABA + LAMA	33 (30.00%)	15 (26.32%)	18 (33.96%)	
LAMA	13 (11.82%)	10 (17.54%)	3 (5.66%)	
Others ^a	10 (9.09%)	5 (8.77%)	5 (9.43%)	
FeNO, ppb	24.00 (16.00,33.00)	22.50 (16.00,34.25)	26.00 (16.00,33.00)	0.605
IgE, IU/mL	73.00 (34.60,181.00)	70.65 (32.60,177.75)	81.20 (37.50,181.00)	0.768
Phadiatop, kU/L	0.07 (0.02,0.26)	0.08 (0.02,0.29)	0.06 (0.02,0.26)	0.881
Leukocytes, ×10 ⁹ /L	7.02 (1.49)	7.11 (1.60)	6.92 (1.36)	0.511
Neutrophils, ×10 ⁹ /L	4.31 (1.20)	4.37 (1.31)	4.25 (1.08)	0.622
Lymphocytes, ×10 ⁹ /L	2.00 (0.63)	2.03 (0.66)	1.98 (0.60)	0.683
Eosinophils, ×10 ⁹ /L	0.16 (0.09,0.24)	0.16 (0.08,0.26)	0.16 (0.10,0.24)	0.688
Erythrocytes, ×10 ¹² /L	4.84 (0.44)	4.88 (0.45)	4.80 (0.43)	0.381
Hemoglobin, g/L	151.81 (12.28)	152.78 (12.33)	150.75 (12.26)	0.389
Platelets, ×10 ⁹ /L	221.82 (49.18)	216.09 (44.58)	228.09 (53.49)	0.204
CAT	13.49 (8.04)	11.59 (8.09)	15.57 (7.51)	0.008
CAT declined	1.38 (6.73)	-3.57 (4.46)	6.79 (4.09)	<0.001

Notes: ^a Others including SAMA, SABA, SAMA+SABA, and no inhalation therapy. All values represent mean (SD) or No. (%) or Median (IQR). Student's *t*-test, Mann-Whitney test, Chi-squared test.

Abbreviations: CAT, COPD assessment test; CAT decline, CAT at baseline – CAT at visit; BMI, body mass index; ICS, inhaled corticosteroids; LABA, long acting beta-agonist; LAMA, long acting muscarinic antagonists; BD, bronchodilator; FVC, forced vital capacity; FEV₁, forced expiratory volume in one second; FeNO, fractional exhaled nitric oxide; IgE, immunoglobulin E.

FeNO Decline Rate Showed Difference Between Two Groups

As shown in Figure 2, we compared the baseline FeNO, FeNO decline values, and the rate of FeNO declined between the symptom improvement and non-improvement groups. The rate of FeNO declined showed significant differences between the two groups, whereas baseline FeNO and FeNO decline values did not.

Association of FeNO Decline Rate with CAT MCID

Logistic regression analysis was performed to identify factors associated with achieving a clinically meaningful improvement in CAT score (Table 2). Univariable logistic regression analysis identified baseline CAT score (OR 1.07, 95% CI 1.02–1.12, $P = 0.011$), BMI (OR 1.12, 95% CI 1.00–1.26, $P = 0.055$), current smoking status (OR 6.90, 95% CI 0.76–62.24, $P = 0.085$), and FeNO decline rate (OR 2.10, 95% CI 1.08–4.09, $P = 0.028$) as potential discriminators of symptom improvement. In the multivariable model, after adjusting for clinically relevant covariates, baseline CAT score (OR 1.06, 95% CI 1.00–1.12, $P = 0.034$) and FeNO decline rate (OR 2.08, 95% CI 1.01–4.29, $P = 0.047$) showed significantly associated with achieving clinically meaningful symptom improvement. BMI showed a borderline association (OR 1.13, 95% CI 1.00–1.29, $P = 0.056$).

ROC Analysis

ROC curve analysis was performed to evaluate the discriminative performance of FeNO decline rate for achieving CAT MCID. AUC of FeNO decline rate, baseline CAT, combined with BMI in discriminating CAT MCID were 0.713 (95% CI 0.617, 0.809) (Figure 3 and Table 3).

Discussion

We retrospectively analyzed 111 patients with COPD, stratifying them into symptom improvement and non-improvement groups based on the CAT MCID. Patients in the symptom improvement group tended to be within higher BMI, higher baseline CAT scores, which reflected more severe clinical status, and a greater FeNO decline rate. Logistic regression analysis identified baseline CAT score and FeNO decline rate as independent factors associated with symptom improvement. ROC curve analysis determined an optimal cutoff value of 23.7% for the FeNO decline rate in discriminating symptom improvement.

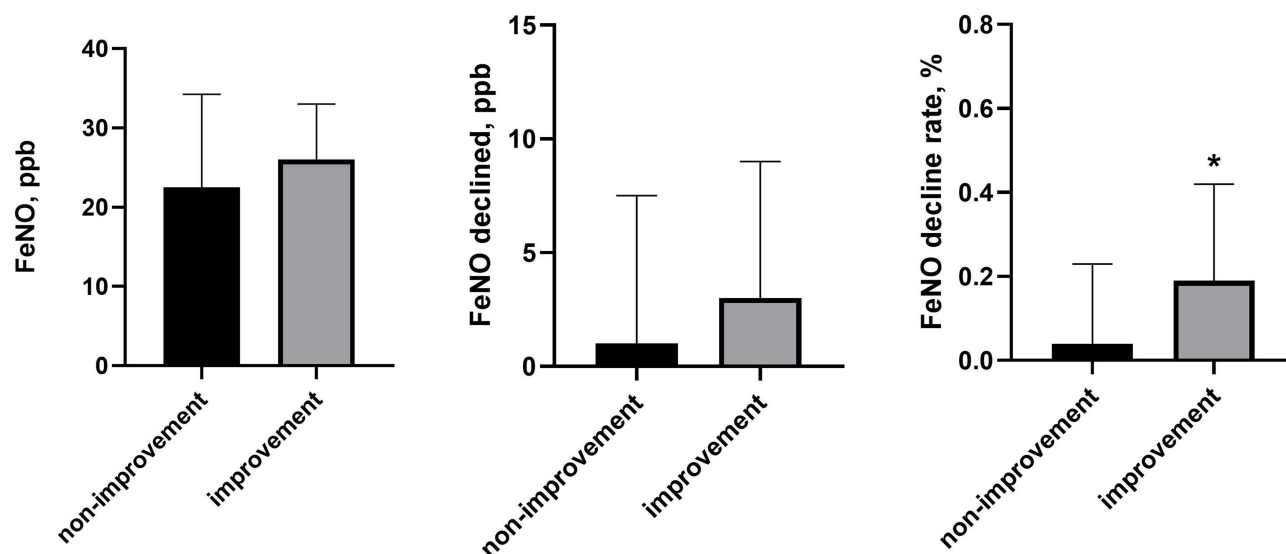


Figure 2 Comparison of baseline FeNO levels and FeNO dynamics between the symptom improvement and non-improvement groups. * $P < 0.05$.

Table 2 Logistic Regression Analysis of Factors Influencing COPD Symptom Improving

Variables	Univariable			Multivariable		
	OR	95% CI	P	OR	95% CI	P
Gender, female	0.26	(0.03, 2.40)	0.235	0.65	(0.04, 9.76)	0.759
Age, year	1.02	(0.96, 1.07)	0.537	1.02	(0.96, 1.10)	0.479
BMI, kg/m ²	1.12	(1.00, 1.26)	0.055	1.13	(1.00, 1.29)	0.056
Current smokers	6.90	(0.76, 62.24)	0.085	4.29	(0.38, 47.92)	0.237
CAT at baseline	1.07	(1.02, 1.12)	0.011*	1.06	(1.00, 1.12)	0.034*
FeNO decline rate, %	2.10	(1.08, 4.09)	0.028*	2.08	(1.01, 4.29)	0.047*

Notes: * $P < 0.05$.

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; BMI, body mass index; CAT, COPD assessment test.

Several studies have reported that higher baseline FeNO is associated with corticosteroid responsiveness.^{8,15,16} However, its discriminative value for clinical outcomes remains inconsistent.^{17,18} In our study, we found that the rate of FeNO declined, rather than baseline FeNO levels or absolute FeNO decline, was associated with achieving the MCID in CAT score. The FeNO decline rate, baseline CAT score, and BMI collectively demonstrated discriminatory ability in identifying CAT MCID. This proportional-response concept is consistent with findings in asthma management, where relative changes in FeNO better reflected treatment effects than absolute values.¹⁹

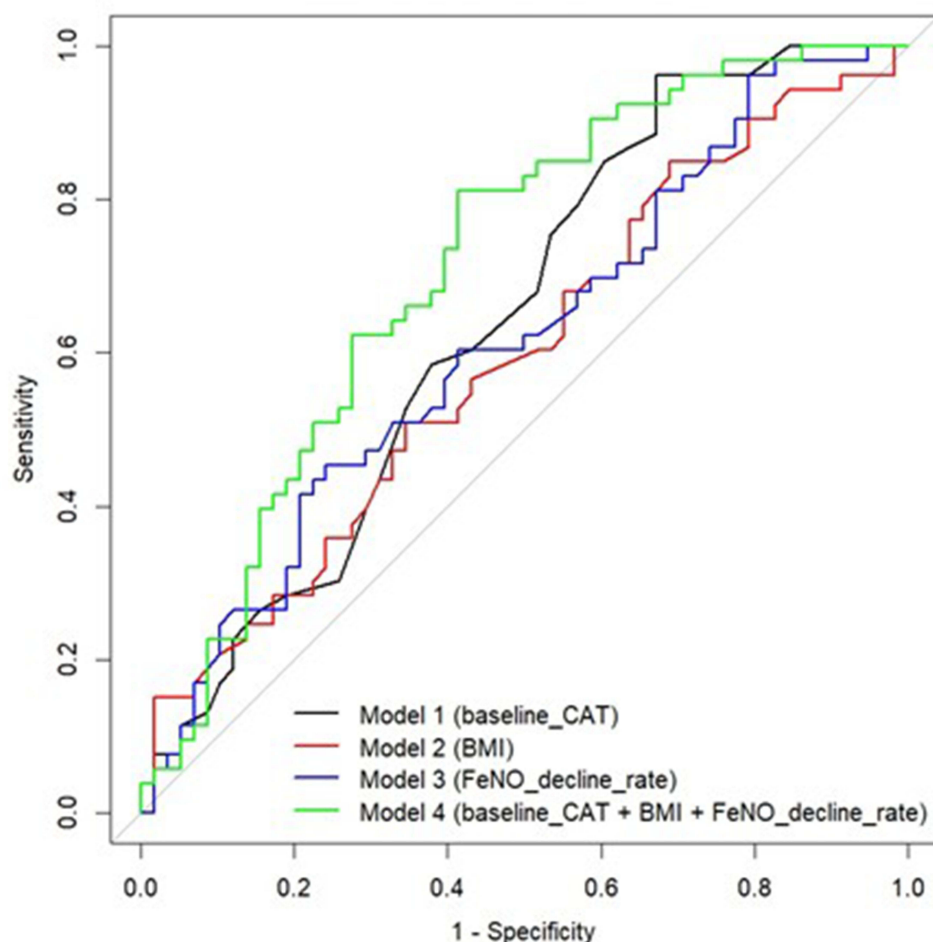


Figure 3 Receiver operating characteristic (ROC) curves of four models for predicting the achievement of a clinically meaningful improvement in CAT score.

Table 3 ROC Curve for Achieving a Clinically Meaningful Improvement in CAT Score

Models	Variables	AUC	95% CI	P-value ^a
Model 1	Baseline CAT	0.642	(0.539, 0.744)	0.54
Model 2	BMI	0.594	(0.488, 0.700)	-
Model 3	FeNO decline rate	0.614	(0.509, 0.719)	0.78
Model 4	Baseline CAT + BMI + FeNO decline rate	0.713	(0.617, 0.809)	0.03

Notes: ^acompared with Model 2.

Abbreviations: CAT, COPD assessment test; BMI, body mass index; FeNO, fractional exhaled nitric oxide.

Compared with static or absolute measures, a rate-based indicator provides a dynamic assessment of airway inflammation, helps normalize inter-patient variability, and more accurately reflects treatment responsiveness. Taken together, these findings reinforce the concept of treatable traits in COPD, emphasizing type-2 inflammation as a modifiable trait.²⁰ Incorporating FeNO decline rate into phenotypic assessment may therefore complement blood eosinophil counts and enhance precision medicine strategies.

Baseline CAT score also influenced the likelihood of achieving clinically meaningful improvement in COPD patients. After adjusting for other covariates, higher CAT scores were positively associated with symptom improvement. This is reasonable, as patients with more severe baseline symptoms are more likely to achieve the threshold of a ≥ 2 -point reduction.²¹

There were several limitations. First, the sample size was modest, which may limit statistical power. Second, treatment regimens were heterogeneous, reflecting real-world practice but potentially introducing confounding effects. Future large-scale, well-controlled studies could better reveal the discriminative utility of FeNO decline rate and validate its role in guiding individualized treatment strategies.

Conclusion

This study suggests that FeNO decline rate was an independent discriminator of clinically meaningful symptom improvement in COPD. The identification of a rate-based biomarker highlights the potential value of dynamic measures of airway inflammation in complementing traditional indicators. These findings provide further support for a treatable traits approach and may contribute to the development of more precise, individualized management strategies for COPD.

Data Sharing Statement

The data used in the current study were obtained from Beijing Chao-yang Hospital, Capital Medical University, which are not publicly available given the data protection policy. However, the Corresponding Author is willing to have further discussion if there are any questions.

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Disclosure

The authors report no conflicts of interest in this work.

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