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ORIGINAL RESEARCH

Blood Eosinophil Counts in Healthy Volunteers and in Patients with Asthma and COPD in India: A Multi-Centre Cross-Sectional Report

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Background: Blood eosinophils have become an invaluable tool in the assessment, management, and prognostication of patients with asthma and chronic obstructive pulmonary disease (COPD). Historically, the understanding and application of blood eosinophil counts (BEC) have been primarily based on data from high-income countries, with limited information available from developing regions, including the Indian subcontinent.

Research Question: This study aims to assess the distribution and clinical relevance of BEC among patients with asthma and COPD as well as healthy volunteers across India, to determine if patterns observed in Western studies hold true in an Indian setting.

Study Design and Methods: A multi-centre cross-sectional study was conducted at 16 clinics across India. Participants included patients diagnosed with asthma or COPD and healthy volunteers who were identified from referrals to these clinics. Comprehensive data collection involved demographics, medication use, smoking status, and pre- and post-bronchodilator spirometry. All participants underwent a laboratory full blood count.

Results: The study comprised 4782 adults, including 1,332 patients with asthma (571 males, 761 females), 1,001 patients with COPD (691 males, 310 females), and 2,449 healthy volunteers (1,399 males, 1,050 females). Among patients with asthma, the mean BEC was higher at geometric mean 173.9 [156.2, 193.6]; patients with COPD had a mean BEC of 198.4 [178.6, 220.4] which was significantly higher than that of healthy volunteers (144.7 [134.5, 155.5]).

Interpretation: The range of eosinophils in the contemporary Indian population aligns with data from Europe, affirming the validity of using BEC as a biomarker in obstructive lung disease within the Indian demographic. This insight challenges the prevailing assumption of distinct eosinophil count profiles in different geographical regions and underscores the global applicability of eosinophil-based management strategies for asthma and COPD.

Keywords: blood eosinophils, eosinophils in COPD, eosinophils in asthma, Indian sub-continent, parasitic infections and eosinophils, eosinophil in men, eosinophil in women, smoking and eosinophils

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Introduction

In the last decade, blood eosinophil count has become an important tool in the management of patients with asthma and COPD. In asthma, it has become the defining feature in the selection of treatments, especially the use of advanced monoclonal antibody therapies for patients with severe asthma.[1] In COPD, the blood eosinophil count has been taken up by international guidelines[2] as a tool to identify patients who are likely to respond to inhaled corticosteroid therapy. It also predicts patients who are likely to have more exacerbations.[3] In population studies, in the UK[4] and South Korea,[5] a raised blood eosinophil count has also been shown to predict the likelihood of patients developing obstructive lung diseases.

Unfortunately, no data exists on the ranges of blood eosinophils counts from people living in India. Treatment guidelines depend entirely on population data derived predominantly from Europe and North America.[6] There is also an assumption that people in India will have a higher mean eosinophil count than people in the global north due to the higher prevalence of parasitic conditions.[7] This perversely makes clinicians in South Asia and other low- and middle-income countries (LMIC) more hesitant to prescribe very cheap therapies such as inhaled corticosteroids to patients who may benefit. This lack of population data is also hindering health funders and pharmaceutical companies from considering the approval of monoclonal antibody therapies for patients in LMIC, further leading to disparities in asthma and COPD outcomes.[8,9]

In this multi-centre cross-sectional observational study, we aimed to assess the mean and range of absolute blood eosinophil counts in patients with asthma and COPD across urban and rural India. We also assessed the blood eosinophil counts in healthy volunteers.

Methods

This cross-sectional study was conducted at 16 secondary care sites across urban and rural India. The geographical locations of the participating centres are shown in Figure 1. The study targeted members of the community who attended these secondary care sites. Healthy volunteers were recruited at participating clinics from community attendees and accompanying family members without clinician-diagnosed chronic lung disease. Screening comprised a structured questionnaire and detailed clinician examination. Participants with a potential cause for raised blood eosinophil other than atopy were excluded. This included but was not limited to suspected or proven parasitic infection, drug allergies,

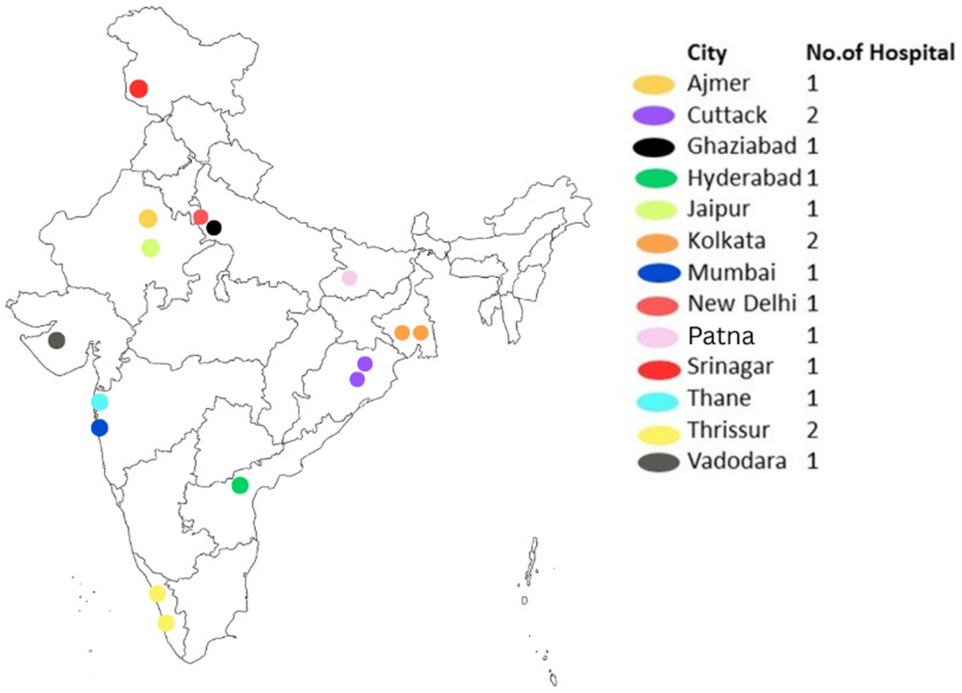

Figure 1 Map of India with recruiting sites.

solid organ malignancies, haematological malignancies, and auto-immune conditions. Patients with any other co-morbidity (other than asthma or COPD) were also excluded. Patients who were anaemic, defined as a haemoglobin count <100g/dL, were excluded. Participants with asthma/COPD were enrolled in a clinically stable state from outpatient clinics of the participating centres; any systemic corticosteroid use within the prior 4 weeks was an exclusion. Atopy was defined a priori as physician-diagnosed allergic disease (eg, allergic rhinitis, eczema, food allergy) and/or prior positive skin-prick testing or allergen-specific IgE when available; no study-mandated tests were performed. Only participants who had completed the full blood count and had completed all the study questionnaires were included. The study was approved by the Institutional Ethics Committee.

Study Assessments

All participants underwent venepuncture for a complete blood count. These samples were run at nationally accredited local laboratories using automated clinical blood counters. When there was a clinical suspicion of lung disease, participants underwent spirometry.[10] Spirometry followed ERS/ATS 2019 standards using locally available, calibrated devices at each site. All participants completed a detailed questionnaire of their medical history and underwent a thorough medical examination.

Statistical Analysis

Data are presented as mean (standard deviation, SD) or median (interquartile range, IQR) for continuous variables, and n (%) for categorical variables. Blood cell counts are summarised as geometric means (GM) with 95% confidence intervals (CI) (and geometric SD where shown in tables). Univariate correlation analyses assessed associations between spirometry indices (FEV1, FVC, FEV1/FVC, FEF25–75) and blood cell counts, separately for asthma and COPD. Multivariate regression analysis was also conducted to assess the relationship between blood eosinophil count and degree of airflow obstruction, adjusting for age, smoking status, and atopic illness. Analyses were conducted in Microsoft Excel (Windows 11). Geometric means were chosen for reporting of the central tendency of leucocyte counts due to the long tail at the upper end of the distribution.[11] Units in the text are reported as cells/μL; Table units are stated in footnotes.

Results

Four thousand seven hundred and eighty-two participants were included in this cross-sectional analysis between 10 August 2021 and 24 July 2022 (see Figure 1). Recruitment and exclusions are shown in Supplementary Figure S1. Mean age was 44.7 (±17) and 2121 (41%) were female. Kernel density distributions by sex are provided in Supplementary Figure S2. About 1332 patients with asthma and 1001 patients with COPD were recruited (Table 1). Most participants (80%) were never smokers.

The geometric mean blood eosinophil count (BEC) for the whole study population was 162.7 [154.4, 171.5] (see Table 2 and Figure 2). Table 3 shows the geometric mean of eosinophil counts across age. Density distributions by age group are shown in Supplementary Figure S3.

Table 1 Baseline Characteristics of Participants

Participant Characteristics	All Participants (n = 4782)	Participants with Spirometry (n = 2333)
Age (years), mean (SD)	44.7(17)	51.67(16.80)
Sex, No. (%)		
Male	2661(55.65)	1262(54)
Female	2121(44.35)	1071(46)
Category of patients No. (%)		
Asthma	1332(27)	1332(57)
COPD	1001(21)	1001(43)
Healthy	2449(52)	NA

(*Continued*)

Table 1 (Continued).

Participant Characteristics	All Participants (n = 4782)	Participants with Spirometry (n = 2333)
Smoking status No. (%)		
Ex-smoker	513(10.72)	414(17.74)
Current smokers	386(8.07)	266(11.40)
Non-smoker	3883(81.20)	1653(70.85)
Comorbidities (%)		
With Atopy	484(10.12)	431(18.47)
Without Atopy	4298(89.88)	1902(81.53)

Table 2 Blood Eosinophil Counts Geometric Mean (Cells/μL) and 95% Confidence Intervals

Parameter	Female (N)	Female GM (95% CI)	Female GSD	Male (N)	Male GM (95% CI)	Male GSD
Total population	2,121	165.7[153.4, 179]	6.14	2,661	160.3[149.2, 172.2]	6.61
Asthma	761	156.9[135.1, 182.4]	8.27	571	199.4[171.7, 231.7]	6.22
COPD	310	243.3[211.5, 279.9]	3.52	691	181.1[157.7, 207.9]	6.38
Healthy	1,050	153.9[138.9, 170.6]	5.50	1,399	138.1[124.9, 152.7]	6.81
Never smokers	2,070	165.9[153.4, 179.5]	6.19	1,813	155.1[141.6, 169.9]	7.25
Smokers (current and former)	51	158.8[107, 235.7]	4.22	848	172[153.7, 192.5]	5.34

In the overall populations, patients taking inhaled corticosteroids had a geometric mean BEC of 184 cells/μL. This was higher compared to participants not prescribed inhaled corticosteroids, geometric mean BEC of 145 cells/μL ($p = 0.002$).

We also assessed for any difference between patients with and without atopy. As expected, participants with atopy had a raised BEC compared to others (geometric mean BEC in atopy compared to non-atopy 213 vs 158 cells/μL) ($p = 0.003$).

Patients with Asthma

In the asthma subset, absolute monocyte count showed a moderate positive correlation with the FEV_1/FVC ratio ($r = 0.37$, $p < 0.001$) and a weak positive correlation with FEF_{25-75} ($r = 0.13$, $p < 0.001$). Absolute neutrophil count demonstrated a weak positive correlation with FEF_{25-75} ($r = 0.13$, $p = 0.0004$). No significant correlations were observed

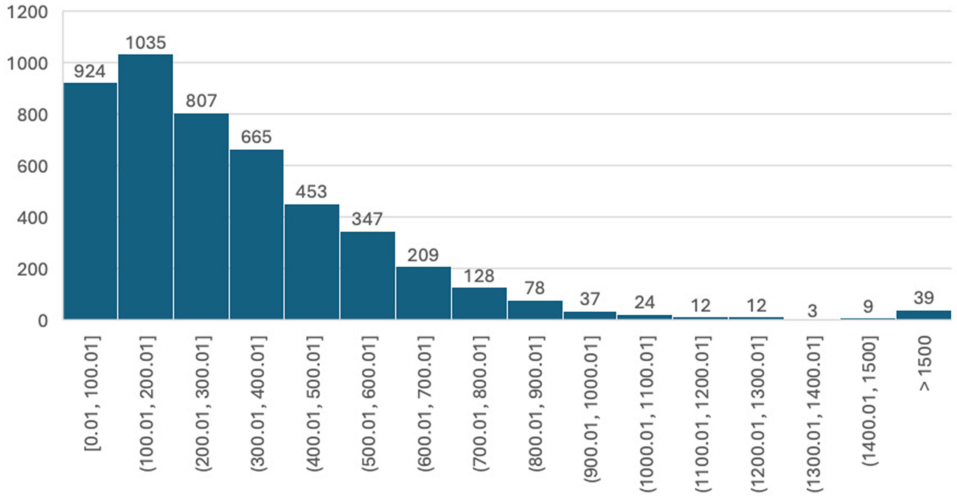

Figure 2 Histogram of the number of patients with available blood eosinophil count in the entire population. The x axis shows the blood eosinophil count (cells/μL) while the y axis shows the frequency.

Table 3 Blood Eosinophil Counts Geometric Mean (Cells/μL) and 95% Confidence Intervals Based on Age

Parameter	≤30 n	≤30 GM (95% CI)	≤30 GSD	31–59 n	31–59 GM (95% CI)	31–59 GSD	≥60 n	≥60 GM (95% CI)	≥60 GSD
Total population	914	112.8[96.3,132.1]	11.42	2,502	173[161.7,185.2]	5.63	1,365	185.4[170.4,201.6]	4.88
Asthma	323	197.8[158,247.6]	7.83	682	163.2[139.5,190.9]	8.07	327	174.9[145,211]	5.64
COPD	19	237[133,422.4]	3.32	336	243.3[208.1,284.5]	4.31	646	177.5[154.4,204.1]	6.12
Healthy	572	80.1[64.8,99.1]	13.41	1,484	164.6[151.8,178.4]	4.90	392	209[191,228.8]	2.49
Never smokers	873	111.2[94.3,131.1]	11.97	2,163	170.5[158.2,183.7]	5.93	846	201.9[184,221.5]	3.96
Smokers (current and former)	41	151.8[112.3,205.1]	2.67	339	190.4[164.8,220]	3.89	519	161.3[137.3,189.5]	6.49

between absolute eosinophil or lymphocyte counts and spirometry indices (Table 4). There was no correlation between the mean blood eosinophil counts within spirometry defined groups of severity in patients with asthma (Table 5)

Patients with COPD

Correlations were confined to FEV1/FVC: neutrophils ($r \approx 0.09$, $p = 0.042$) and lymphocytes ($r \approx 0.12$, $p = 0.008$) showed weak positive associations, whereas monocytes showed a weak negative association ($r \approx -0.18$, $p < 0.001$). There were no significant correlations between eosinophils and any spirometry index, and no associations with FEV1 or FEF25–75 for any cell type (see Tables 6 and 7).

Multivariate Analysis

Multivariate analyses were conducted for patients with asthma and COPD. Overall, in patients with asthma, BEC only contributed 3.28% of the variance in FEV1 ($F(4,679) = 5.762$), $P < 0.001$). Similarly, in patients with COPD, there was no correlation between blood eosinophil counts and FEV1, accounting for 0.453% of the variance in FEV1.

Discussion

We have shown in a large multi-centre cross-sectional study that the distribution of blood eosinophil counts amongst healthy volunteers, participants with asthma and COPD in India is consistent with North American, European, and East Asian cohorts. Published cohorts from Europe/North America and East Asia report broadly similar blood eosinophil count (BEC) in asthma and COPD. Our Indian distributions align with these ranges, supporting the transferability of

Table 4 Pearson's Correlation Between Spirometry Measures and Blood Granulocyte Counts in Patients with Asthma

	FEV1/FVC		FEV1		FEF25–75	
	R_value	P_value	R_value	P_value	R_value	P_value
Absolute Eosinophil count	0.1751	0.0000	−0.0079	0.8369	0.0343	0.3708
Absolute Neutrophil count	0.0289	0.4503	0.0309	0.4205	0.1340	0.0004
Absolute Lymphocyte count	−0.0256	0.5041	−0.0019	0.9595	0.0064	0.8675
Absolute Monocyte count	0.3704	0.0000	0.0701	0.0670	0.1326	0.0005

Table 5 Pearson's Correlation Between FEV1 (L) and Mean Blood Eosinophil Counts Within Spirometry Defined Groups of Severity in Patients with Asthma

FEV1% Predicted	Severity	n	Mean BEC (SD), Cells/μL	R	p-value
< 50%	Severe	267	163.27 ± 85.60	0.016	0.838
50–80%	Moderate	527	151.00 ± 41.17	0.454	0.349
> 80%	Mild	538	207.13 ± 23.36	0.027	0.569
All	Total	1332	185.72 ± 31.60	0.025	0.412

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Table 6 Pearson's Correlation Between Spirometry Measures and Blood Granulocyte Counts in Patients with COPD

	FEF25–75		FEV1/FVC		FEV1	
	R_value	P_value	R_value	P_value	R_value	P_value
Absolute Eosinophil count	0.01341	0.76931	0.06222	0.173	0.02342	0.60843
Absolute Neutrophil count	0.01743	0.70297	0.09269	0.042	−0.02696	0.55536
Absolute Lymphocyte count	0.01722	0.70636	0.12127	0.008	0.05873	0.19852
Absolute Monocyte count	−0.04776	0.29584	−0.17839	< 0.001	−0.03605	0.43019

Table 7 Pearson's Correlation Between FEV1 (L) and Mean Blood Eosinophil Counts Within Spirometry-Defined Groups of Severity in Patients with COPD

FEV1% Predicted	Severity	n	Mean BEC (SD), Cells/μL	R	p-value
< 50%	Severe	447	190.39 ± 31.02	0.050	0.344
50–80%	Moderate	351	183.76 ± 40.47	0.059	0.034
> 80%	Mild	203	315.42 ± 43.59	0.015	0.877
All	Total	1001	202.17 ± 22.13	0.428	0.255

guideline-endorsed eosinophil thresholds to clinical practice decision-making in India. This finding contradicts the outdated notion that patients in India have a higher blood eosinophil count due to more prevalent undiagnosed enteric parasitic infections.[7]

The blood eosinophil count is now an established biomarker to help identify patients with obstructive lung disease with a T helper 2 cell (T_h2) predominant endotype. In asthma, this biomarker is the key tool to help identify patients who will benefit from advanced monoclonal antibody therapies such as mepolizumab[12] and benralizumab.[13] In COPD, guidelines now recommend the use of blood eosinophil counts to help identify patients who benefit from inhaled corticosteroid therapy.[2] This has been proven in retrospective cohorts[3] and in prospective randomised controlled trial data.[14,15] Patients with COPD with a raised blood eosinophil count have also been identified to be at higher risk of frequent exacerbations. The blood eosinophil count has also been tested in guiding the use of systemic corticosteroids for the management of COPD exacerbations,[16–18] helping physicians safely identify patients who will not benefit from unnecessary corticosteroid treatment. Physicians in India should be alerted to the one in five patients with a blood eosinophil count greater than 300 cells/μL who are at highest risk of exacerbations.

Of particular interest were the sex-based differences in mean BEC in healthy volunteers, patients with asthma or in patients with COPD. Unlike our findings, previous work in European datasets[19] and international meta-analyses[20] showed higher blood eosinophil counts in men compared to women. This sex-based difference is in keeping with the higher reported rates of atopic conditions and asthma in adult women.[21]

As expected, patients with atopy had a higher blood eosinophil count compared to patients without. This is consistent with international datasets that consistently show a relationship between atopy and mean blood eosinophil count.[22] Participants with atopy account for up to 25% of participants in the original NHANES dataset than has been used to define the normal BEC range. This has been postulated to be the reason for the normal range to include eosinophil counts of up to 500 cells/μL.

In our cohort, participants prescribed inhaled corticosteroids had a higher mean BEC compared to those who were not. Consistent with large datasets, we did not find a lower blood eosinophil count in patients with asthma prescribed inhaled corticosteroids.[23] Similarly, our data is consistent with other work showing no effect of inhaled corticosteroids on blood eosinophil counts in patients with COPD.[24]

Additionally, we investigated the relationship between spirometry measurements and blood eosinophil counts. Again, consistent with previous data, there was no relationship between blood eosinophil count and measures of airflow obstruction. This further reinforces the understanding of the value of blood eosinophils in asthma and COPD care.

Blood eosinophils reflect the degree of inflammatory activity and the risk of exacerbations. Spirometry defined measures of severity probably better reflect the duration of illness and existing fixed airflow obstruction from previously undertreated inflammation and exacerbations.

Our study has some limitations. Recruitment from established clinical settings may introduce selection bias related to health-seeking behaviour and economic factors; these were not systematically captured. Spirometry was available only for a subset of participants with asthma and COPD and was not routinely performed in healthy volunteers, so undiagnosed obstructive lung disease in the latter cannot be excluded. Another limitation of this analysis is the use of linear regression for the univariate and multivariate analyses. As full blood count data is generally logarithmic, there is potential that these analyses violate the underlying statistical assumptions of these methods. The cross-sectional design precludes assessment of temporal variability. No study-mandated tests for atopy were performed.

Conclusion

In a large multicentre Indian cohort, BEC distributions for healthy adults, asthma, and COPD are comparable to international datasets. These findings support the use of guideline-recommended eosinophil thresholds to guide management in India.

Abbreviations

BEC, Blood Eosinophil Count; COPD, Chronic Obstructive Pulmonary Disease; ICS, Inhaled Corticosteroids; FEV1, Forced Expiratory Volume in One Second; FVC, Forced Vital Capacity; CI, Confidence Interval; SD, Standard Deviation; IQR, Interquartile Range; ERS, European Respiratory Society; ATS, American Thoracic Society; GSK, GlaxoSmithKline (if mentioned in the context of funding or research support); IRB, Institutional Review Board; GM – Geometric mean; GSD, Geometric standard deviation; FEF25–75, Forced expiratory flow between 25% and 75% of FVC; GOLD, Global Initiative for Chronic Obstructive Lung Disease; GINA, Global Initiative for Asthma; LMIC, Low- and middle-income countries; NHANES, National Health and Nutrition Examination Survey; Th2, T helper 2.

Ethics Statement

Institutional Ethics Committee, The Calcutta Medical Research Institute Approval Number: IEX/01/2021/ACD/EXP-APR/03 dated 22 April 2021. All participants were informed about the purpose of the study and provided written informed consent in accordance with the Declaration of Helsinki (2013).

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Disclosure

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PK declares no research grant received by him which are related or Unrelated to this study/work/project/research.

Unrelated to this study/work/project/research, PK declares speaker fees from Pharmaceutical companies like Cipla, Lupin etc. PK declares his association with Zydus pharma. PK also declares about having Patents – but all are Unrelated to this study/work/project/research.

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