The impact of COPD Type 2 Inflammation and the Consequences on Outcomes in the Brazilian Private Healthcare System: A Real-World Analysis

COPD

Jacob-Ferreira LB[1], Nascimento MHS[1], Herrera EM[2], Magro F[1], Watanabe SF[1]

[1]Sanofi, SP, Brazil; [2]Sanofi, Cambridge, MA, USA.

Background

- Chronic obstructive pulmonary disease (COPD) significantly impacts morbidity and mortality worldwide and is one of the leading causes of death in Brazil.[1,2]
- Studies have shown that patients with COPD often present with elevated levels of eosinophils (EOS),[3,4] which serve as a biomarker for type 2 inflammation (T2I). Additionally, 20% to 40% of patients with COPD exhibit T2I, which may increase the likelihood of exacerbation and lung function impairment.[5]
- Despite the high burden of COPD in Brazil, there have been limited real-world data on the burden of COPD in patients with T2I.

Objective

- **To explore the burden of COPD type 2 inflammation in patients with COPD with a high blood eosinophil count (≥300/µL; high EOS).**

Conclusions

- **In this retrospective analysis of real-world data, COPD patients with high-EOS (≥300/µL) demonstrated significant unmet medical needs, exhibiting a high proportion of medical encounters, including ambulatory, emergency department (ED), and inpatient visits, as well as increased mortality.**
- **This underscores the need for effective management strategies to address the heightened burden of COPD in patients with T2I.**
- **The results should be interpreted with caution due to the retrospective nature of this study. Additionally, there may be unmeasured confounding factors that could bias the results.**

METHODS & RESULTS

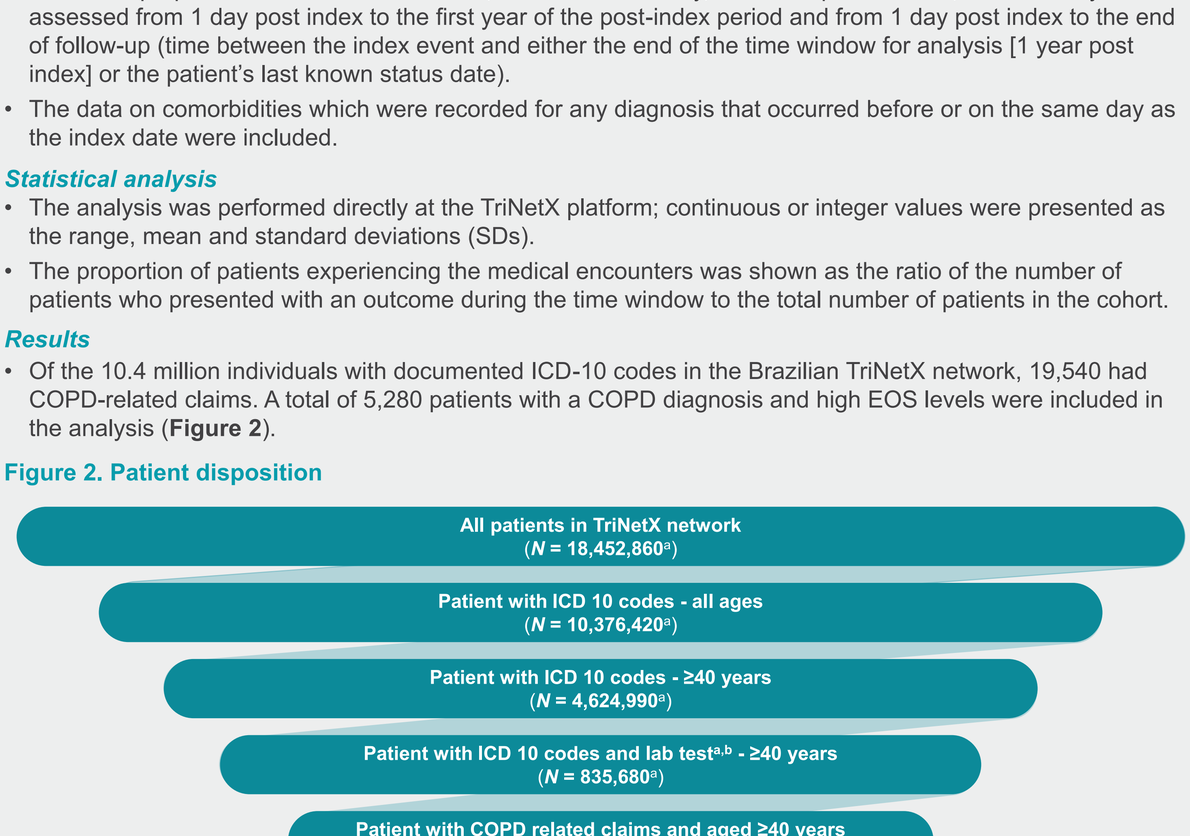
Data source

- This retrospective cohort study utilised the TriNetX real-world database, which consists of anonymised patient data from 22 private Brazilian healthcare organisations and includes information on 18,452,860 patients. This corresponds to 35% of the Brazilian private market and approximately 5% of the total Brazilian population.

Study population

- Eligible participants were adults (aged ≥40 years) with a documented record of COPD (ICD-10 codes J41 to J44) and a high EOS count (≥300/µL) between January 2016 and April 2024.
- The 'index date' referred to the date when a patient first met the criteria of COPD diagnosis and had high EOS levels during the patient selection window.
- Blood EOS count records available within 6 months before or after COPD diagnosis were considered.
- Patients with secondary ICD-10 codes (B65-B83, T78.4, J45, E27.1 and C81-C96), known as hypereosinophilic syndrome, were excluded. The study design is depicted in **Figure 1**.

Figure 1. Study design



[a]The index date referred to the date when a patient first met the criteria of COPD diagnosis and had high EOS levels during the patient selection window.
[b]Comorbidities included any diagnoses that occurred before or on the same day as the index date.
[c]The follow-up period was defined as the time between the index date and either the end of the analysis window (1 year post index) or the patient's last known status date.
COPD, chronic obstructive pulmonary disease; EOS, eosinophils.

Outcomes

- Increased proportion of medical encounters, such as ambulatory, ED and inpatient visits, and mortality were assessed from 1 day post index to the first year of the post-index period and from 1 day post index to the end of follow-up (time between the index event and either the end of the time window for analysis [1 year post index] or the patient's last known status date).
- The data on comorbidities which were recorded for any diagnosis that occurred before or on the same day as the index date were included.

Statistical analysis

- The analysis was performed directly at the TriNetX platform; continuous or integer values were presented as the range, mean and standard deviations (SDs).
- The proportion of patients experiencing the medical encounters was shown as the ratio of the number of patients who presented with an outcome during the time window to the total number of patients in the cohort.

Results

- Of the 10.4 million individuals with documented ICD-10 codes in the Brazilian TriNetX network, 19,540 had COPD-related claims. A total of 5,280 patients with a COPD diagnosis and high EOS levels were included in the analysis (**Figure 2**).

Figure 2. Patient disposition

[a]Patient counts were rounded up to the nearest 10 to protect PHI. Rounding might influence measures of association results of small cohorts and infrequent Outcomes.
[b]Blood EOS count occurring within 6 months before or after any instance of COPD.
COPD, chronic obstructive pulmonary disease; EOS, eosinophils; ICD, International Classification of Diseases; *N*, total number of patients; PHI, protected/personal health information.

- The mean age of patients was 72.7 (SD: 11.6) years, with 52% being male. The average EOS count was 350/µL (SD: 370) (**Figure 3**).
- Major comorbidities at the index date included cardiovascular (46%), certain infections and parasitic diseases (24%) digestive (22%), genitourinary (22%), neoplasms (19%) and diabetes mellitus (10%) (**Table 1**).

Figure 3. Baseline demographic and clinical characteristics at the index date in patients with high-EOS COPD

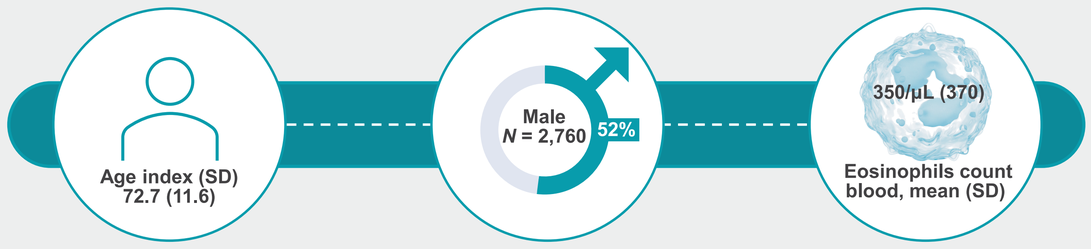


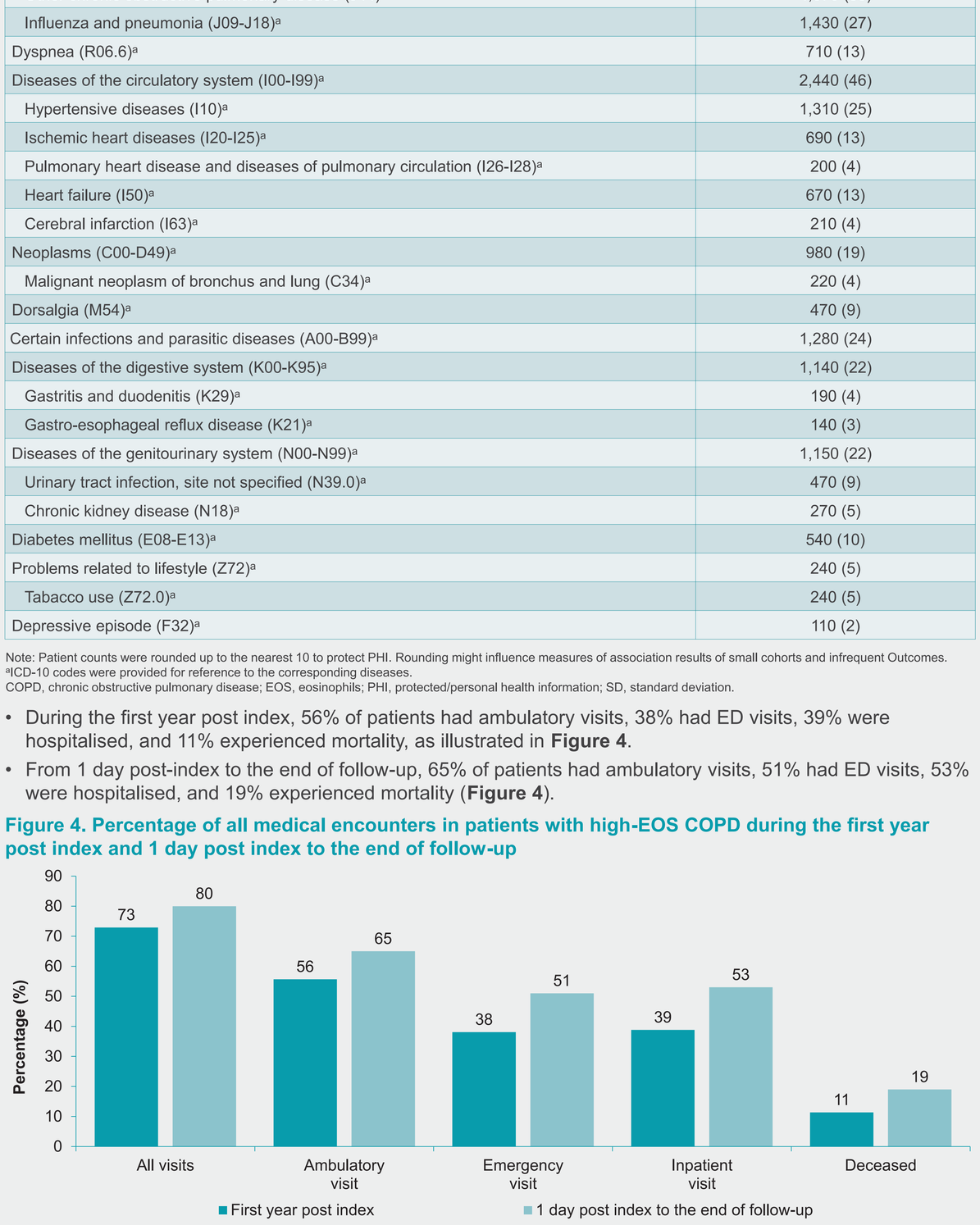
Table 1. Comorbidities at the index date in patients with high-EOS COPD

Comorbidities, *n* (%)	High-EOS COPD *N* = 5,280
Diseases of the respiratory system (J00-J99)[a]	5,280 (100)
Simple and mucopurulent chronic bronchitis (J41)[a]	80 (2)
Unspecific chronic bronchitis (J42)[a]	200 (4)
Emphysema (J43)[a]	520 (10)
Other chronic obstructive pulmonary disease (J44)[a]	4,670 (88)
Influenza and pneumonia (J09-J18)[a]	1,430 (27)
Dyspnea (R06.6)[a]	710 (13)
Diseases of the circulatory system (I00-I99)[a]	2,440 (46)
Hypertensive diseases (I10)[a]	1,310 (25)
Ischemic heart diseases (I20-I25)[a]	690 (13)
Pulmonary heart disease and diseases of pulmonary circulation (I26-I28)[a]	200 (4)
Heart failure (I50)[a]	670 (13)
Cerebral infarction (I63)[a]	210 (4)
Neoplasms (C00-D49)[a]	980 (19)
Malignant neoplasm of bronchus and lung (C34)[a]	220 (4)
Dorsalgia (M54)[a]	470 (9)
Certain infections and parasitic diseases (A00-B99)[a]	1,280 (24)
Diseases of the digestive system (K00-K95)[a]	1,140 (22)
Gastritis and duodenitis (K29)[a]	190 (4)
Gastro-esophageal reflux disease (K21)[a]	140 (3)
Diseases of the genitourinary system (N00-N99)[a]	1,150 (22)
Urinary tract infection, site not specified (N39.0)[a]	470 (9)
Chronic kidney disease (N18)[a]	270 (5)
Diabetes mellitus (E08-E13)[a]	540 (10)
Problems related to lifestyle (Z72)[a]	240 (5)
Tabacco use (Z72.0)[a]	240 (5)
Depressive episode (F32)[a]	110 (2)

Note: Patient counts were rounded up to the nearest 10 to protect PHI. Rounding might influence measures of association results of small cohorts and infrequent Outcomes.
[a]ICD-10 codes were provided for reference to the corresponding diseases.
COPD, chronic obstructive pulmonary disease; EOS, eosinophils; PHI, protected/personal health information; SD, standard deviation.

- During the first year post index, 56% of patients had ambulatory visits, 38% had ED visits, 39% were hospitalised, and 11% experienced mortality, as illustrated in **Figure 4**.
- From 1 day post-index to the end of follow-up, 65% of patients had ambulatory visits, 51% had ED visits, 53% were hospitalised, and 19% experienced mortality (**Figure 4**).

Figure 4. Percentage of all medical encounters in patients with high-EOS COPD during the first year post index and 1 day post index to the end of follow-up



Note: Patient counts were rounded up to the nearest 10 to protect PHI. Rounding might influence measures of association results of small cohorts and infrequent Outcomes.
COPD, chronic obstructive pulmonary disease; EOS, eosinophils; PHI, protected/personal health information.

REFERENCES

1. Santo AH and Fernandes FLA. *COPD: J Chronic Obstruct Pulmonary Dis* 2022.19: 216–225.
2. Moreira ATAd. *et al. J Brasileiro de Pneumol* 2021. 48: e20210120.
3. Landis S. *et al. COPD: J Chronic Obstruct Pulmonary Dis* 2018. 15: 177–184.
4. Kolsum U. *et al. Euro Resp J* 2019: 54: 1900633.
5. Bhatt SP. *et al. New Eng J Med* 2023. 389: 205–214.

ACKNOWLEDGEMENTS

Medical writing support was provided by Umesh Mahajan and Ali Nasir Siddiqui from Sanofi.

FUNDING

The study was sponsored by Sanofi and Regeneron Pharmaceuticals Inc.

CONFLICTS OF INTEREST

JL, NM, HE, MF and **WS** are employees of Sanofi and may hold stocks and/or stock options in the company.

Poster presented at the International Society for Pharmacoeconomics and Outcomes Research Europe 2024 (ISPOR EU 2024), 17–20 November, Barcelona, Spain.