Lifetime prevalence of Type 2 comorbidities in patients with COPD: especially those with higher eosinophilic counts

First published: 31/10/2025

Last updated: 31/10/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000792

Study ID

1000000792

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This real-world evidence study employs a retrospective cohort design using data from the OPCRD dataset to compare the prevalence of Type 2 (T2) inflammation-related comorbidities in individuals with COPD and those with T2 asthma. The study population includes three groups: COPD-only, asthma-only, and patients with both COPD and asthma, with further stratification based on blood eosinophil counts. Inclusion criteria require individuals aged 20 and above, diagnosed using spirometry and medical coding, while those with overlapping chronic respiratory conditions (e.g., cystic fibrosis) are excluded. Primary outcomes include the prevalence and incidence of T2 comorbidities, analyzed through lifetime prevalence, pre-diagnosis prevalence, and incidence within five years post-diagnosis. Statistical analyses include descriptive statistics, Poisson regression models for prevalence comparisons, and Kaplan-Meier curves to assess cumulative incidence. Sensitivity analyses will address missing eosinophil data and rounding biases by refining eosinophil count categories. The findings will provide insights into the relationship between eosinophilic inflammation and comorbidities, aiding in personalized treatment approaches for COPD patients with T2 features.

Study status

Planned

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

David Price dprice@opri.sg

Study contact

dprice@opri.sg

Primary lead investigator

David Price 0000-0002-9728-9992

Primary lead investigator

ORCID number:

0000-0002-9728-9992

Study timelines

Date when funding contract was signed

Planned: 28/01/2025

Study start date

Planned: 10/01/2025

Date of final study report
Planned: 31/05/2025

Sources of funding

- Other public funding (e.g. hospital or university)

More details on funding

University of Exeter

Study protocol

Protocol_2413.pdf (408.61 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Retrospective cohort study using the Optimum Patient Care Research Database (OPCRD).

Main study objective:

• Compare the lifetime prevalence of T2-related comorbidities (e.g., allergic rhinitis, nasal polyps, atopic dermatitis) among patients with COPD (with and without T2 inflammation) and those with asthma.

• Assess the prevalence of T2-related comorbidities in individuals before the diagnosis of COPD or asthma.

• Evaluate the incidence of T2-related comorbidities within a fixed 5-year period following the diagnosis of COPD or asthma.

• Stratify the study population based on blood eosinophil, count categories and examine trends in T2 comorbidities across these strata.

• Perform sensitivity analyses addressing the rounding biases in blood eosinophil counts.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

All the COPD-patients with confirmed diagnosis FEVC1/FVC ratio <70% and who do not have recorded history of asthma at any time either previous or concurrent and

2) All the asthma patients only regardless of their spirometry results and who do not have history of COPD at any time either previous or concurrent

3) COPD comorbid asthma previous or concurrent

4) For COPD-only and asthma-only patients the first ever recorded date of

diagnosis will be their index date. For COPD comorbid asthma group, the index date will be the date when COPD was first diagnosed or when both COPD and asthma were first documented together. The timing of asthma diagnosis (whether before or after COPD) does not change the fact that the index date is based on the first COPD diagnosis as COPD is the primary condition and focus of the study.

5) To be eligible for inclusion, individuals must be 18 years or older at the index date

6) All of these people will be limited to those diagnosed within the last 10 years with at least 1 year of follow-up, i.e. patients diagnosed between 01/01/2013-01/01/2024. This would ensure that only patients diagnosed on or before 01/01/2024 will be included to have at least 1 year of follow-up.

7) All of these COPD-only, asthma-only and COPD-comorbid asthma patients should be registered at the OPCRD surgery during diagnosis.

8) At least 12 months of registration at participating GP surgery prior to index date

---

Age groups

- Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)

Special population of interest, other

Patients with COPD, Patients with asthma, patients with COPD with comorbid asthma

---

Estimated number of subjects

228143

Study design details

Setting

This is a retrospective cohort study using the Optimum Patient Care Research Database (OPCRD). The OPCRD is an electronic primary care record database covering more than 1,000 GP surgeries across England, Scotland, Wales and Northern Ireland.

Comparators

The patients with COPD having type 2 related comorbidities such as allergic rhinitis and atopic dermatitis will be compared with asthma patients with type 2 inflammation.

Outcomes

T2-related comorbidities included in this study will encompass a range of conditions that have been associated with T2 inflammation, including

• allergic rhinitis,

• atopic dermatitis,

• chronic rhinosinusitis,

• nasal polyps,

• allergic rhinitis,

• eosinophilic esophagitis,

• ulcerative colitis

Data analysis plan

The first step will be to summarize the demographic and clinical characteristics of the study population. This will include means, medians and frequencies for continuous and categorical variables, stratified by the three groups: COPD only, asthma only, and COPD-asthma comorbid, to help us understand the distribution of the data or imbalances across the groups.

The lifetime prevalence of Type 2-related comorbidities (e.g., atopic dermatitis, allergic rhinitis, etc.) will be analyzed using Poisson regression with robust variance.

Prevalence prior to COPD/Asthma diagnosis: For assessing prevalence prior to diagnosis, we will examine records of Type 2 comorbidities before the first diagnosis of COPD or asthma. The prevalence rate ratio will be calculated using Poisson regression with robust variance, both unadjusted and adjusted for potential confounders.

Cumulative incidence: Kaplan-Meier curves will be used to estimate the cumulative incidence of Type 2 comorbidities over time, stratified by the three groups (COPD only, asthma only, and COPD-asthma comorbid). The analysis will focus on the incidence 5 years post-diagnosis as specified, and Kaplan-Meier survival functions will be estimated for each group. The log-rank test will be used to compare the survival curves between the groups.

Age standardization: Since the three groups may differ in terms of age distribution, age standardization will be performed to adjust for these differences. The standardization will involve creating an age-standardized rate by weighing the incidence rates in each group according to a reference population (e.g., the overall study population). This process will help to

eliminate any age-related biases and provide a fairer comparison between the groups. After age standardization, we will run the entire analysis again to ensure that any observed differences in prevalence, incidence, or comorbidity rates are not due to age adjustment on the observed results.

Summary results

The work will be published in a peer-reviewed journal.

Data management

ENCePP Seal

> The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Optimum Patient Care Research Database

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No