Clinical characteristics, use and switch of drugs for obstructive airway diseases among patients with COPD experiencing an exacerbation: a retrospective analysis of Italian administrative healthcare data

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000623

Study ID

1000000623

DARWIN EU® study

No

Study countries

Italy

Study description

Background: In Italy, the pharmaceutical care of COPD patients is still ill-timed and inaccurate.

This study aimed to describe the treatment of COPD patients in Italy and possible switches following an exacerbation.

Methods: This observational retrospective analysis of Italian administrative healthcare data from the ReS database identified patients aged ≥45 years with COPD in 2019 and 2020. At least 6 years of look-back period and absence of concomitant asthma were required. COPD patients were categorized by treatment (SI–single/MI–multiple inhalers, TT–triple therapy, DT–dual therapy, other respiratory treatments, untreated) at index date (first dispensation during accrual period).

Occurrence of moderate/severe exacerbation during one-year preceding index date and treatments during one-year preceding the exacerbation (possible switch) were evaluated. Results From ~ 4.7 million beneficiaries of the Italian National Health Service in 2019 and 2020, respectively, 105,828 and 103,729 (43 and 41 × 1,000 inhabitants aged ≥ 45 years) were identified as having COPD. Of 2019/2020 patients: 3.4%/5.2% received SI-TT, 20.7%/17.5% MI-TT, 35.9%/38.1% DT, 33.0%/33.1% other treatments, and 7.0%/6.0% were untreated. Males were prevalent and median age was > 73 years for all groups. Of 2019/2020 cohorts, heart failure and coronary artery disease affected 24/20%, 18/17%, and 11%/16% patients with SI-TT, MI-TT, DT, and other treatments, respectively.

A previous moderate/severe exacerbation (2019/2020 patients) occurred to 60.5%/56.6%, 39.9%/37.4%, 30.8%/29.2% and 31.9%/29.7% patients treated with SI-TT, MI-TT, DT, and other treatments, respectively. Of 2019/2020 patients experiencing moderate/severe exacerbation: 6.0%/7.0% receiving DT, 5.1%/7.0% receiving other treatments and 4.5%/10.0% untreated, switched to SI-TT; 23.7%/16.9% receiving DT, 21.4%/17.7% receiving other treatments and 15.4%/12.0% untreated, switched to MI-TT.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

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Institution **Not-for-profit** **ENCePP partner**

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 11/01/2023

Study start date
Actual: 14/02/2023

Date of final study report
Actual: 11/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This report received unconditional funding from Astra Zeneca S.p.A. The financial support for this study was provided with a funding agreement ensuring maintenance of author independence in study design, data interpretation, writing, and decisions to publish.

Regulatory

Was the study required by a regulatory body?
No

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

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Patients aged ≥ 45 years with COPD were identified in 2019 and in 2020.
A look-back (until 2014) was required. Different groups by dispensed treatment strategy for COPD were analysed in 1 year before index to assess exacerbations and in 1 year before exacerbation to assess eventual therapy switch

Main study objective:

This descriptive retrospective observational cohort study of Italian administrative healthcare data aimed to identify patients with COPD and describe them in terms of treatment approach in 2019 and 2020, and how treatment strategies changed following an acute exacerbation, in the light of the GOLD guidelines of the time and soon after the marketing and reimbursement in Italy of the SI-TT.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Additional medical condition(s)

Exacerbations of chronic obstructive pulmonary disease

Population studied

Short description of the study population

From the ReS database, including Italian inhabitants and beneficiaries of the SSN, patients aged ≥ 45 years, variously distributed throughout northern, central and southern Italy, and with at least 6 years of look-back period (i.e., analysed until 2013) were identified.
The study population was categorized according to the first treatment strategy for COPD dispensed in the accrual periods into the following cohorts: patients treated with TT (SI or MI), DT (SI or MI), other treatment strategy with drugs for obstructive airway diseases.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

Study design details

Setting

Italian inhabitants and beneficiaries of the SSN which is a universal coverage health system. Two overall observation periods: 2014-2020 and 2014-2021. Patients with asthma during the accrual periods were excluded. Inhospital/local outpatient settings.

Summary results

From ~ 4.7 million beneficiaries of the Italian National Health Service in 2019 and 2020, respectively, 105,828
and 103,729 (43 and 41 × 1,000 inhabitants aged ≥ 45 years) were identified as having COPD. Of 2019/2020 patients: 3.4%/5.2% received SI-TT, 20.7%/17.5% MI-TT, 35.9%/38.1% DT, 33.0%/33.1% other treatments, and 7.0%/6.0% were untreated.
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Documents

Study publications

L Dondi, G Ronconi, S Calabria, I Dell’Anno, L Dondi, C Piccinni, O Brignoli, G...

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)

Database of Fondazione ReS

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown