Acute lower respiratory infections: real-world evidence of antibiotic prescription pattern and costs from a large administrative Italian database

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Study   Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000187

EU PAS number

EUPAS1000000187

Study ID

1000000187

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Through this retrospective observational analysis of the Fondazione ReS (Ricerca e Salute) database, collecting Italian healthcare administrative data, antibacterial for systemic use supplied to subjects aged ≥12 years in 2017 were identified as potentially prescribed to treat an acute exacerbation of chronic obstructive pulmonary disease (AECOPD) (39,940; 91%) or an event of community-acquired pneumonia (CAP) (4,059; 9%). The most used antimicrobials were quinolones (37.2% and 39.0% of antibiotics related to AECOPD and CAP, respectively), third-generation cephalosporins (25.5%; 27.5%), penicillins (15.4%; 14.9%), and macrolides (14.4%; 11.3%). Costs of each patient supplied with the antibacterial to treat AECOPD/CAP were assessed within 30 days after the antibacterial supply. Overall, the integrated cost of the association AECOPD/CAP-antibacterial was higher if the patient was hospitalized due to AECOPD/CAP before the antibacterial supply (€5,006/€4,966, respectively). The integrated expenditure of a patient treated for AECOPD not requiring hospitalization was €647. Findings showed a substantial antimicrobial use in Italy for the 2 acute lower respiratory tract infections, highlightening the need of improving the current prescribing practice or developing new molecules. This study also provided healthcare integrated costs of these associations as a proxy of the complexity and frailty of patients experiencing an AECOPD/CAP event.

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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Study timelines

Date when funding contract was signed

Actual: 15/01/2020

Study start date

Actual: 01/02/2020

Date of final study report

Actual: 03/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This research was partially supported by an unconditional grant from Zambon Italy. Zambon Italy was not involved in data collection, analysis, and interpretation, in writing the report, nor in deciding to submit the article for publication.

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

The prescription pattern was assessed for patients with an AECOPD (aged ≥50) or a CAP event (aged ≥12) in 2017. A 30-day cost analysis after the antibacterial supply and according to absence/presence (15 days before/after the supply) of AECOPD/CAP hospitalization was performed.

Main study objective:

This observational retrospective analysis aimed to describe antibiotic prescription pattern in patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD) and community-acquired pneumonia (CAP) and their costs, from the Italian National Health Service perspective.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01) ANTIBACTERIALS FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

Medical condition to be studied

Lower respiratory tract infection

Population studied

Short description of the study population

Subjects analysable up to the end of 2018, aged ≥12 years and supplied with at least one antibacterial for systemic use (ATC code:J01) from January 01, 2017 to December 31, 2017 (accrual period) were selected.

Age groups

Adolescents (12 to < 18 years)

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

Inpatient and outpatient

Summary results

In 2017, among patients aged ≥12 (~5 million), 1,845,268 were supplied with ≥1 antibacterial (37.2%). Antibacterial prescriptions potentially related to AECOPD were 39,940 and 4,059 to CAP: quinolones were the most prescribed (37.2% and 39.0%, respectively), followed by third-generation cephalosporins (25.5%; 27.5%), penicillins (15.4%; 14.9%), and macrolides (14.4%; 11.3%); the 30-day mean cost was €709 and €2,889. An association AECOPD/CAP-antibacterial supply costed more when the hospitalization occurred 15 days after the antibiotic supply (€5,006 and €4,966, respectively).

Documents

Study publications

Acute lower respiratory infections: real-world evidence of antibiotic prescript...

Data management

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

Yes