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Screening for chronic obstructive pulmonary disease (COPD) in patients hospitalized with chronic complex diseases. Utility of FEV1/FEV6 index for the diagnosis of chronic obstructive pulmonary disease, and prognostic implications

Submission date
23/05/2019

Recruitment status
No longer recruiting

Registration date
28/05/2019

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic respiratory diseases account for an important percentage of multimorbidity, although compared with other chronic diseases, pulmonary disorders are often underdiagnosed. The causes of this misdiagnosis are, among others, the lack of suspicion and the need to perform valid spirometry (a measurement of the speed of the air that is exhaled) to confirm the diagnosis of many of them, such as COPD. Although spirometry is a simple and widely available technique, its performance in frail elderly patients can be difficult, especially due to the inability to maintain expiratory flow until complete exhalation. Depending on the population studied, between 20 and 80% of elderly patients are unable to complete satisfactory spirometry.
In recent years, several handheld spirometers have been developed. Usually, these spirometers measure the FEV1/FEV6 ratio, requiring less effort and allowing the recovery of the 25% of patients unable to complete forced vital expiration. These devices have proven useful in the screening of respiratory obstruction and have shown an excellent correlation with conventional spirometry. However, current evidence of the utility of FEV1/FEV6 for the diagnosis of airway obstruction in multimorbid patients hospitalized for decompensation of chronic diseases is scarce.
Our main objective was to study the utility and reliability of FEV1/FEV6 in the diagnosis of pulmonary obstruction in patients hospitalized with multimorbidity, and the variables associated with the inability to successfully perform valid manoeuvers to determine the FEV1/FEV6 with COPD-6 and FEV1/FVC with conventional spirometry.

Who can participate?
Patients hospitalized for any cause in the complex chronic patient care unit at University Hospital Mutua de Terrassa with ≥ 2 chronic diseases.

What does the study involve?
On the last day of hospitalization patients or their caregivers completed a questionnaire that included medical and socioeconomic variables, smoking history, prior diagnosis of chronical respiratory disease, results of the most recent spirometry if available, and domiciliary treatment. Measurement of the functional parameters, FEV1, FEV6, and FEV1/FEV6 ratio, was performed the last day of hospitalization, using the portable COPD-6 device and a portable spirometer.

What are the possible benefits and risks of participating?
The study does not suppose any risk to the patient since the maneuvers (FEV1/FEV6 and standard spirometry) are innocuous and the rest of the data are already usually collected in our unit according to good clinical practice. The potential benefits are the reduction of underdiagnosis in these patients and the possibility of initiating bronchodilator treatment in patients with airflow obstruction.

Where is the study run from?
Complex chronic patient care unit Universitary Hospital Mutua de Terrassa, Spain.

When is the study starting and how long is it expected to run for?
September 2017 to May 2018

Who is funding the study?
Complex chronic patient care unit Universitary Hospital Mutua de Terrassa, Spain.

Who is the main contact?
Prof. Pere Almagro
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PAM-000-2017-01

Study information

Scientific Title
Screening for COPD in patients hospitalized with chronic complex diseases. Utility of FEV1/FEV6 index for the diagnosis of chronic obstructive pulmonary disease, and prognostic implications.

Study objectives
1. Patients hospitalized in the care unit for chronic complex patients from the Internal Medicine department of the University Hospital Mutua de Terrassa will present a high prevalence of pulmonary obstruction measured by FEV1/FEV6 index, and this will be confirmed with a subsequent standard spirometric test.
2. The presence of cognitive impairment (measured with short portable Pfeiffer test, Global Deterioration Scale (GDS), MMSE, and intersecting pentagon copying component of the MMSE) or functional impairment (measured with the Barthel index) will be associated with a lower probability of completely valid determination of FEV1/FEV6.
3. The presence of pulmonary obstruction measured by FEV1/FEV6 index and confirmed by subsequent standard spirometry, and the severity of the disease assessed with the post-bronchodilator FEV1%, will be associated with a worse prognosis in the medium term (1-year) defined as hospital readmission or death after hospital discharge.
4. Of the patients able to undergo measurement of the FEV1/FEV6 index, approximately 20% cannot complete a quality spirometry according to the criteria of the American Thoracic Society.
5. Patients with a greater burden of comorbidity – defined according to the functional definition of polypathological patient criteria of the Andalusia Health Department and the Charlson index – will present a greater prevalence of obstructive pulmonary criteria measured by the FEV1 /FEV6 index and subsequently confirmed by complete spirometry.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/05/2017, Ethical research committee, Hospital Universitario Mutua de Terrassa (Dr. Jordi Nicolas Pico, C/ Sant Antoni 39, Terrassa 08221, Barcelona, Spain; 34-937365050 ext 11032; jnicolas@mutuaterrassa.cat)

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not availabke in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease in patients with multimorbidity

Interventions
On the last day of hospitalization patients or their caregivers completed a questionnaire that included medical and socioeconomic variables, smoking history, prior diagnosis of chronical respiratory disease, results of the most recent spirometry if available, and domiciliary treatment. Multimorbidity assessment was evaluated using the multimorbidity classification of the Andalusia Health Department, the Charlson index and a scale for other comorbid conditions not included in the Charlson index. Physical functional status was assessed with the Barthel index, while cognitive status was measured using the Pfeiffer test and the Mini-Mental Cognitive Examination in the Spanish version of Lobo et al.
Measurement of the functional parameters, FEV1, FEV6, and FEV1/FEV6 ratio, was performed the last day of hospitalization, using the portable COPD-6 device (model 4000, Vitalograph Ltd., Ennis, Co. Clare, Ireland) and a portable spirometer. (Datoespir micro, Sibelmed, Barcelona Spain).

Intervention Type
Other

Primary outcome measure
Prevalence and underdiagnosis of obstructive pulmonary disease, as measured by FEV1 / FEV6 and confirmed by subsequent spirometry in patients hospitalized in the complex chronic patient care unit. Measurement of the functional parameters, FEV1, FEV6, and FEV1/FEV6 ratio, was performed the last day of hospitalization, using the portable COPD-6 device (model 4000, Vitalograph Ltd., Ennis, Co. Clare, Ireland) and a portable spirometer. (Datoespir micro, Sibelmed, Barcelona Spain).

Secondary outcome measures
Variables are associated with the inability to successfully perform valid maneuvers to determine the FEV1/FEV6.
1. A questionnaire that included medical and socioeconomic variables, smoking history, prior diagnosis of chronical respiratory disease, results of the most recent spirometry if available, and domiciliary treatment.
2. Multimorbidity assessment was evaluated using the multimorbidity classification of the Andalusia Health Department, the Charlson index and a scale for other comorbid conditions not included in the Charlson index.
3.Physical functional status was assessed with the Barthel index.

4. Cognitive status was measured using the Pfeiffer test and the Mini-Mental Cognitive Examination in the Spanish version of Lobo et al.
All measures were completed on the last day of hospitalisation.

Overall study start date
15/01/2017

Completion date
31/05/2019

Eligibility

Key inclusion criteria
Patients hospitalized for any cause in the complex chronic patient care unit at University Hospital Mutua de Terrassa with ≥ 2 chronic diseases according to the functional definition of polypathological patient of the Andalusia Health Department.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
200

Total final enrolment
184

Key exclusion criteria
1. No written informed consent to participation in the study.
2. Death during hospitalization.
3. Other reasons, apart from cognitive or functional impairment, which prevent the realization of FEV1/FEV6 (e.g., tracheotomy, facial paralysis….)

Date of first enrolment
01/09/2017

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
Spain

Study participating centre
Complex chronic patient care unit Universitary Hospital Mutua de Terrassa
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Sponsor information

Organisation
Mutua Terrassa

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Sponsor type
Hospital/treatment centre

Website
https://www.mutuaterrassa.com

ROR
https://ror.org/02h74qa12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/05/2019

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/07/2017		Yes	No
Results article	results	02/08/2019	12/05/2020	Yes	No
Dataset		02/08/2019	14/06/2023	No	No