Feasibility of the assessment of ventricular function in patients with an exacerbation of COPD, within 24 hours of admission

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Can mobile echocardiographic and pulmonary function measurements be performed adequately and patient-friendly within 24 hours after admission to hospital and before discharge in COPD patients aged 65 years or over with an exacerbation?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON31482

Source
ToetsingOnline

Brief title
Ventricular dysfunction in exacerbation of COPD.
EXACT-study

Condition

- Heart failures
- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COPD, exacerbation, Left ventricular dysfunction, Right ventricular dysfunction

Outcome measures

Primary outcome

Participants will receive the usual investigations and treatment necessary in case of an exacerbation. After written informed consent, participants will additionally undergo a pulmonary function test including spirometry with flow-volume curves and echocardiographic assessment within 24 hours of admission. Left and right sided left ventricular function will be assessed. As is already common practice in the UMC Utrecht, blood tests will include measurements of plasma B-type natriuretic peptide (BNP), and high sensitive C-reactive protein at admission and discharge. Echocardiography and blood analysis will be repeated before discharge (about 7 days after admission). Echocardiographic and spirometric measurements will be performed at the bed-side with mobile apparatuses at the time the patient is clinically stabilised. It is common practice in the pulmonary department of the UMC Utrecht to perform blood tests including measurements of C-reactive protein (CRP) and plasma B-type natriuretic peptide.

Outcome measures:

- How many echocardiograms and spirometric measurements could be performed completely and adequately?

- Are the results of these measurements interpretable (using a mobile bed-side apparatus in patients experiencing dyspnoea)?
-What is the median (with 25-75% interquartile range) on the visual analoge scale from 0-10, with 0= no burden at all, and 10= extremely burdensome?

To provide participants the most optimal possible treatment, possibly including cardiovasvcular therapy, in all participants an expert panel will establish presence or absence of ventricular dysfunction or heart failure (i.e. ventricular dysfunction and symptoms indicative of heart failure). The panel consisting of 2 cardiologists, a pulmonologist and a general practitioner (10) will use all available diagnostic information including pulmonary function test, echocardiographic results, and plasma B-type natriuretic peptide levels. Earlier studies have shown that panel diagnoses in heart failure are highly reproducible. (10;11) The panel will use the diagnostic criteria for heart failure recommended by the European Society of Cardiology.(12)

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(12) Swedberg K, Cleland J, Dargie H, Drexler H, Follath F, Komajda M et al.

Guidelines for the diagnosis and treatment of chronic heart failure: executive summary (update 2005): The Task Force for the DIagnosis and Treatment of Chronic Heart Failure of the European Society of Cardiology. Eur Heart J 2005;26:1115-40.

Secondary outcome

none

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is a prevalent disease that is on the increase, and is one of the leading causes of death world-wide.(1) Patients with this disease frequently experience exacerbations which greatly affect the quality of life and health of these patients, and place a great burden on health services.(2) Nowadays, there is no precise definition of an exacerbation of COPD.(2) An exacerbation of COPD is characterised by an abrupt increase in symptoms. Increased dyspnoea and increased sputum volume and purulence are generally seen as cardinal symptoms during an exacerbation.(2) Narrowing of airways and worsening of oxygen saturation can be expected.(2) The changes in lung function associated with exacerbations is generally small, but importantly, lasting for up to three months.(2) In-patient mortality from exacerbation range from 4 to 30%,(3) and mortality of patients with COPD is independently related to the frequency of severe exacerbations.(4) The one year mortality rate after admission in a US study was 43%, and heart failure was an independent predictor of mortality.(5) Until now, attention has focussed on bacteria, viruses, atypical micro-organisms such as mycoplasma and chlamydia pneumoniae, and environmental pollution as causes for exacerbations of COPD.(6) However, only in about half of the exacerbations there is objective evidence of infection. Thus, additional factors seem to have a causal role in the development of an exacerbation. Such an additional causal factor could be (short lasting) ventricular dysfunction (left and/or right). The importance of left ventricular dysfunction in stable primary care patients with COPD has recently been demonstrated by our group.(7) Importantly, in the majority of the patients with COPD concomitant heart failure (i.e. ventricular dysfunction with symptoms indicative of heart failure) was previously unknown.
Indeed, overlap in symptoms and signs are important, ready at hand reasons for not recognising heart failure in patients with COPD. However, also the fact that hospitalised patients with COPD are treated by pulmonologists and those

with heart failure by cardiologists certainly influences the 'general neglect' of concomitant presence of both syndromes.
Information about the left ventricular dysfunction during an exacerbation of COPD is scarce, but prevalences of left ventricular systolic dysfunction of 20-30% have been reported.(8;9) These studies, however, were not performed within 24 hours of hospital admission for an exacerbation of COPD, and did not include diastolic dysfunction, right ventricular dysfunction, or follow-up measurements. Moreover, feasibility of new bedside echocardiography facilities has never been reported. Therefore, the question whether measurements within 24 hours by bed-side echocardiography is feasible and produces interpretable results is unanswered, as is the question whether diastolic dysfunction or right ventricular dysfunction can be assessed in such acute dyspnoeic patients in a semi-sitting position.

(1) Murray CJ, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. Lancet 1997;349:1498-504.
(2) Donaldson GC, Wedzicha JA. COPD exacerbations. 1: Epidemiology. Thorax 2006;61:164-8.
(3) Patil DP, Krishnan JA, Lechtzin N, Diette GB. In-hospital mortality following acute exacerbation of chronic obstructive pulmonary disease. Arch Intern Med 2003;163:1180-6.
(4) Soler-Cataluna JJ, Martinez-Garcia MA, Romaln SP, Salcedo E, Navarro M, Ochando R. Severe exacerbations and mortality in patients with chronic obstructive pulmonary disease. Thorax 2005;60:925-31.
(5) Connors AF, Jr., Dawson NV, Thomas C, Harrell FE, Jr., Desbiens N, Fulkerson WJ, et al. Outcomes following acute exacerbation of severe chronic obstructive lung disease. The SUPPORT investigators (Study to Understand Prognoses and Preferences of Outcomes and Risks of Treatments). Am J Respro Crit Care Med 1996;154:959-67.
(6) Sapey E, Stockley RA. COPD exacerbations. 2: Aetiology. Thorax 2006;61:250-8.
(7) Rutten FH, Cramer MJ, Grobbee DE, Sachs AP, Kirkels JH, Lammers JW, Hoes AW. Unrecognized heart failure in elderly patients with stable chronic obstructive pulmonary disease. Eur Heart J 2005;26:1887-94.
(8) Render ML, Weinstein AS, Blaustein AS. Left ventricular dysfunction in deteriorating patients with chronic obstructive pulmonary disease. Chest 1995;107:162-8.
(9) McCullough PA, Hollander JE, Nowak RM, Storrow AB, Duc P, Omland T et al. Uncovering heart failure in patients with a history of pulmonary disease: rationale for the early use of B-type natriuretic peptide in the emergency department. Acad Emerg Med 2003;10:198-204.

Study objective

Can mobile echocardiographic and pulmonary function measurements be performed adequately and patient-friendly within 24 hours after admission to hospital and before discharge in COPD patients aged 65 years or over with an exacerbation?

Study design

A cross-sectional diagnostic pilot study will be conducted in 20 consecutive patients admitted at the pulmonary department of the University Medical Center (UMC) Utrecht for an exacerbation of COPD. Patient burden will be assessed by a visual analoge scale from 0-10, with 0= no burden at all, and 10= extremely burdensome.

Study burden and risks

There is no risk associated with participation. Echocardiographic measurements with radio frequency waves and spirometric measurements can be performed without risk.
Participants will undergo the usual history taking, physical examination, additional investigations and treatment as is necessary in patients with an exacerbation of COPD. As is common practice. Participants will additionally undergo a bedside echocardiogram and spirometry within 24 hours after admission at a time that he/she is clinically stable. Echocardiographic measurements will be repeated before discharge. By using mobile echocardiography and spirometry, with measurements at the bedside, the burden for the participants will be as small as possible (no transport to the laboratory, no waiting time).
Participants can profit when (newly detected) ventricular dysfunction or heart failure is established, because they will receive adequate evidence-based morbidity and mortality reducing cardiovascular treatment. There is no direct group related benefit. Only when this pilot study shows that a large scale study is feasible and our hypothesis is confirmed that ventricular dysfunction and heart failure is common in these patients, then adjustment of the routine diagnostic assessment of these patients and treatment should be changed in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with COPD, aged 65 years or over, who experience an exacerbation for which admission to the hospital is necessary.

Exclusion criteria

Patients with COPD, already known with a diagnosis of heart failure (assessment including echocardiography), patients unable or unwilling to give written informed consent, patients experiencing an exacerbation of COPD, however aged less than 65 years.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	26-09-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18805.041.07