Validation of 2 methods of continuous cardiac output measurement during exercise in patients with chronic heart failure: LiDCO and Physioflow

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON30666

Source
ToetsingOnline

Brief title
CO validation study

Condition

- Heart failures

Synonym
chronic heart failure, left ventricular dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum

Source(s) of monetary or material Support: Pfizer,wetenschapsfonds MMC

Intervention

Keyword: bioimpedance cardiography, cardiac output measurement, exercise testing, pulse contour analysis

Outcome measures

Primary outcome

Difference and agreement between lithium dilution and direct Fickk method at

rest.

Difference and agreement between PulseCO, Physioflow and the direct Fick

method.

Secondary outcome

not applicable

Study description

Background summary

Patients with chronic heart failure (CHF) suffer from exercise intolerance, which is caused by abnormal skeletal muscle metabolism and a decrease in cardiac output during exercise. Information on the cardiac output response during exercise can lead to a better understanding of the relative contribution of central and peripheral factors to the exercise capacity of individual CHF patients. In addition, measuring cardiac output during exercise can be useful for clinical purposes like measuring effects of therapeutic interventions (e.g. exercise training, cardiac resynchronization therapy, stem cell therapy) and predicting the response to exercise training.
Recently, 2 new methods of continuous CO measurement were introduced: LiDCO (LiDCO Group) and Physioflow (Manatec Biomedical). Since both methods were not validated during exercise in patients with CHF the aim of the present study is to compare these methods with the (continuous) direct Fick method and continuous thermodilution during submaximal and maximal exercise.

Study objective

The aim of the present study is to compare two methods for measuring continuous cardiac output (LiDCO and Physioflow) with the direct and continuous Fick method and continuous thermodilution during submaximal and maximal exercise in patients with CHF .

Study design

First a symptom-limited exercise test and on another day in the same week 2 submaximal constant-load tests (at 30% and 50% of the previously determined maximal workload) followed by a second symptom-limited exercise test. The latter tests include cardiac output measurements. Before these tests a 7.5 F catheter (CCOmbo, Edwards, Irvine, USA) is introduced into the pulmonary artery through the right or left antecubital vein at the Cardiac catheterization room (under local anaesthesia); the position of the catheter is verified by fluoroscopy. In addition, a short catheter is inserted into the radial artery of the same side.
During the exercise tests LiDCO and Physioflow are compared to a gold standard method (direct Fick method). LiDCO is based on arterial pulse pressure waveform analysis and Physioflow is a non-invasive bioimpedance method, based on the principle that variation in the impedance to flow of a high-frequency, low-magnitude alternating current across the thorax results in the generation of a measured waveform from which stroke volume can be calculated.
The direct Fick method is performed by measuring oxygen uptake, mixed venous and arterial oxygen saturation continuously.

Study burden and risks

Insertion of pulmonary artery catheter (ventricular arrhytmias, hematoma, local thrombosis) and radial artery catheter (hematoma, dissection).
Exercising with a pulmonary artery catheter was performed in previous studies without complications.

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

Stable chronic heart failure due to myocardial infarction or dilating cardiomyopathy NYHA II-III left ventricular ejection fraction < 40%

Exclusion criteria

Exclusion criteria:
Factors that potentially influence the accuracy of the measurements:
- Lithium use
- Weight < 40 kg
- Atrial fibrillation / flutter
- Aortic aneurysm, aortic regurgitation
- Orthopaedic, pulmonary, neuromuscular or other conditions that influence the ability to exercise
- Chronic obstructive pulmonary disease (COPD) with FEV1/FVC < 60%
Factors that potentially increase the risk:
- Pregnancy
- Change of NYHA stage or medication in the last 2 months
- Myocardial infarction < 3 months before inclusion
- Unstable angina at rest with STT changes
- Severe aortic stenosis, hypertrophic obstructive cardiomyopathy, myocarditis
- Hypertension at rest (systolic >200 mmHg , diastolic > 100 mmHg)
- Prosthetic valve
- Atrial or ventricular thrombus
- Thrombo-embolic events in the past

- Positive Allen*s test

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2007
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	13-03-2007
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL15770.015.06