Acute effects of exercise in heart failure - a pilot study

Published: 23-11-2012
Last updated: 26-04-2024

The primary aim of this project is to investigate acute effects of moderate- and high-intensity exercise in heart failure patients and their age- and sex-matched controls on retrograde and antegrade shear in the brachial artery, expressed in the...

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

Summary

ID

NL-OMON37247

Source
ToetsingOnline

Brief title
Acute effects of exercise in heart failure

Condition

- Heart failures

Synonym
decompensatio cordis, heart decompensation, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Fysiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Exercise, Heart failure, Regional blood flow, Shear stress

Outcome measures

Primary outcome

Brachial artery blood flow patterns during leg exercise; retrograde and

antegrade shear rate, expressed in oscillatory index.

Secondary outcome

Thermoregulatory changes (skin and core body temperature)

Autonomic function (heart rate variability)

Cardiac troponin-release and N-terminal B-type natriuretic peptide concentration

Heart rate and blood pressure

Study description

Background summary

Aging of the population and prolongation of lives has led to an increase in the prevalence of chronic diseases such as heart failure. Heart failure (HF) is a syndrome characterized by a variety of abnormalities, such as a low exercise tolerance, reduced exercise-induced blood flow and endothelial dysfunction and autonomic nerve dysfunction characterized by an enhanced sympathetic activation.14, 17 Despite improvements in pharmacological therapy, HF is a disease with a high morbidity and mortality and poses a large financial burden on the society. Exercise training is a promising new therapy for improvement of symptoms and prognosis in heart failure.1-4 Recent studies have revealed that high-intensity training results in a larger improvement in physical fitness in HF patients than traditional moderate-intensity training.1, 5 As the changes in local and systemic physiological factors represent principle stimuli for vascular adaptation to exercise training, better insight into these acute effects of exercise is of special importance.

One of the most important stimuli for vascular adaptation relates to the exercise-induced increase in shear stress in the active and inactive regions.9 In peripheral conduit arteries, the blood flow pattern varies during one

cardiac cycle. The large antegrade component during systole is followed by a retrograde component in early diastole.18 Shear stress elicited during exercise is an important stimulus for vascular adaptations, with antegrade shear being related to improvement in vascular function whilst the retrograde component is thought to exert a proatherogenic effect on the endothelium.9, 11 To date, no previous study compared shear pattern responses to acute moderate and high-intensity exercise.

Previous studies in healthy volunteers found that leg cycling exercise is associated with an increased retrograde flow in upper body arteries during the initial phase of exercise probably owing to sympathetic vasoconstriction.19 This discrepancy at the onset of exercise disappears when continuing exercise, resulting in an attenuation of the retrograde shear rate when skin temperature increases during prolonged exercise.10 As HF patients experience an enhanced sympathetic nerve activity and a disturbed thermoregulation characterized by attenuated cutaneous vasodilator responses to heating, the reversal of the retrograde flow during exercise could be delayed.12-14 This different response can have important implications for the development of effective exercise training programs for HF patients. To our knowledge, no previous study performed a comprehensive comparison of the acute responses to exercise between healthy control and heart failure. Differences in these responses may prevent heart failure patients to optimally benefit from exercise training.

Study objective

The primary aim of this project is to investigate acute effects of moderate- and high-intensity exercise in heart failure patients and their age- and sex-matched controls on retrograde and antegrade shear in the brachial artery, expressed in the oscillatory index, using non-invasive echo-Doppler.

Study design

Subjects will report to the laboratory on 3 separate days. After performance of a maximal cycling test on day 1, subjects perform 2 bout of exercise (high and moderate-intensity). The order of day 2 and 3 will be randomized between subjects. Six hours prior to day 2 or 3, subjects ingest a telemetric temperature pill to record core body temperature, whilst also skin temperature on the lower arm will be examined. After cannulation of the antecubital vein, a 10-minute rest will be implemented. Heart rate (HR), blood pressure (RR), heart rate variability (HRV) will be registered and a venous blood sample will be drawn before and at pre-determined time points after the exercise intervention. During exercise, brachial artery blood flow will be assessed by Duplex ultrasound. A continuous registration of forearm skin temperature and core body temperature will be acquired during the whole study protocol. Tests will be performed at the same time of day and under the same conditions (>24 h no exercise, >18 h no coffee/tea/chocolate/alcohol/vitamin C). Subjects are

instructed to ingest a meal about 2 hours before testing, which will be kept similar between both exercise days.

Day 1 (2h)
• Medical screening
• Incremental maximal cycling test

Day 2/3 (2.5h)
• An antecubital vein is cannulated for blood sampling for determination of troponin
• Start of continuous registration of skin and core body temperature
• Baseline measurement of heart rate, blood pressure and HRV
• Venous blood sampling
• Exercise session with ultrasound measurement of brachial artery blood flow and continuous registration of heart rate
• Measurement of heart rate, blood pressure and HRV at 0, 30 and 60 minutes post-exercise
• Venous blood sampling at 0, 30 and 60 minutes post-exercise
• Stop continuous registration of skin and core body temperature 60 minutes post-exercise

Study burden and risks

The cannulation of the antecubital vein can induce a haematoma (~5%). However, this is completely reversible within 2 weeks and will not lead to permanent damage.

Exercise training is not associated with a health risk. Moreover, exercise training typically causes a decreased cardiovascular risk, whilst vascular and cardiac function and structure improve after a period of exercise training. Also a number a previous studies have demonstrated that the cardiac workload during high intensity training is not significantly different to the (traditional) moderate-intensity training and can be safely applied in subjects with cardiovascular disease or impaired cardiac function.15, 16 Therefore, both types of exercise are associated with a cardiac load that is typically used during heart failure/cardiac rehabilitation, whilst it also suggested that it is not associated with an increased risk for development of health-related problems. Nonetheless, all exercise sessions will be attended by or supervised by a trained exercise physiologists and/or physiotherapist and/or physician. The presence of a physician in the room is dependent on the age and medical status of the participants.Moreover, subjects will be monitored using a Polar heart rate monitor continuously during every training session, whilst each training session will be performed at the hospital. This will ensure that all exercise training sessions are performed in a well-controlled environment in the unlikely case that medical assistance is necessary before, during or after the exercise session.

Also the blood flow measurements with the ultrasound technique and temperature measurements are not related to any potential risk.

The telemetric temperature pill (CorTempTM) is registered at the Food and Drug Administration (FDA) for 22 years.31 No negative incidents regarding the ingestion of the CorTempTM are reported after distribution of 35.000 pills. The Department of Physiology has extensive experience with core body temperature measurements using the CorTempTM (>1000 measurements). We have not experienced any negative consequences in our participants.

At the department of Physiology, we have a long-standing tradition in performing all previously mentioned tests (maximal cycling test, heart rate variability measurements, blood flow measurements and temperature monitoring). All procedures are performed routinely at the Department of Physiology and have been accepted by the ethics committee in numerous previous applications. Moreover, there is a long history of performing exercise training studies at our department.

Contacts

Public
Selecteer

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL
Scientific
Selecteer

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient group
- Patients diagnosed with heart failure NYHA class II/III
- >= 18 years of age
- Mentally able/allowed to give informed consent;Control group
- Subjects free of cardiovascular disease and/or cardiovascular medication
- >= 18 years of age
- Mentally able/allowed to give informed consent

Exclusion criteria

- Contra-indications for exercise testing
- Serious co-morbidity;For the telemetric temperaturepill, additional exclusioncriteria have been formulated.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2013

Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	23-11-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL41067.091.12