Effects of combined strength and endurance training on hemoglobin mass in patients with heart failure. A randomized controlled trial.
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Introduction

Heart failure is a growing public health issue (Owan et al., 2006; Zaeian and Forasare, 2016). It is a multifactorial and systemic disease in which the dysfunction of the heart muscle leads to volume overload and circulatory redistribution (Tanai & Frantz, 2015). In the final stage, the heart is no longer able to provide the body with an adequate supply of blood. Patients with heart failure often show iron deficiency and anaemia, which is manifested by a decrease in serum hemoglobin concentration.

In addition to drug treatment, exercise training is an effective therapy for patients with heart failure and is therefore recommended in the guidelines (recommendation level I, evidence level A). Exercise increases physical performance through positive effects on the heart muscle, skeletal muscles and the vascular system (Hakowsky et al., 2013; Pandey et al., 2015). Physical training in heart failure is associated with an improvement in quality of life and a reduction in hospitalization and mortality rates.

Studies on healthy volunteers have shown a significant influence on training on the blood profile. An increase in the absolute volumes of blood plasma and erythrocytes was observed (Sawka et al., 2000; Bonne et al., 2014; Montero et al., 2015). In heart failure these parameters have not been investigated. Only concentration-dependent blood parameters have been determined so far (Sander et al., 2014). Determining the effect of training on erythrocyte volume and hemoglobin mass in heart failure patients could significantly improve the understanding of the underlying mechanisms and encourage new therapeutic strategies.

The aim of the proposed study is therefore to describe for the first time the exercise-induced changes in blood volume, hemoglobin mass and hemodynamic parameters in patients with heart failure.

Methods

| Study design: | Randomized controlled intervention trial |
| Study group: | Patients with heart failure NYHA class I |
| Ethical approval: | The study will be approved by the Ethical Committee at the Medical Faculty. |
| Inclusion criteria: | Patients with heart failure 18 years and older (ICD I50) |
| Intervention group: | The patients in the interventions group receive an individualized strength and endurance training program over 12 months. |
| Control group: | The patients of the control group (IG) are diagnosed and receive information on lifestyle changes and standard care. |
| Measurements: | Echocardiography, blood pressure, stress ECG with spiroergometry and impedance cardiology, diagnosis of anemia (blood analysis), blood volume and hemoglobin mass determination with a CO-rebreathing method |
| CO-method: | The carbon monoxide (CO) method is based on the indicator dilution principle. CO binds almost completely to hemoglobin. Therefore, the increase in carboxyhemoglobin (COHb) after the inhalation of a defined amount of CO is inversely related to the hemoglobin mass (HmMass). In commonly used CO rebreathing protocols the CO is administered as a bolus into a rebreathing circuit. In our new CO-method the patients inhaled a CO-air mixture (1500 ppm) for a specific breathing duration. The benefit is a linear increase in COHb. |
| Statistical analysis: | Statistical comparisons are performed using a two-way repeated measures analysis of variance. |
| Case number: | Power = 0.8; two-sided; alpha = 0.05; expected hemoglobin mass change approx. 6% = 54 g (Schmidt and Prommer, 2008; Montero et al., 2015; Montero et al., 2017); 83 patients per group (IG and CG); a total of 222 subjects are enrolled (including dropouts) |

Placing
- Planning contracts
- Training project staff
- Ethics vote
- Process scheduling

Study conduct
- Preparation period
- Recruitment
- Data acquisition
- Data evaluation
- Data publication

Pre period | Project period | Post period
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Visit | V1 | V2 | V3 |
Month | 0 | 3 | 6 |
Randomization | | |
Baseline | | | |
Follow-up | | | |
End of Study | | | |

Figure 1: Study flowchart

Prospects and impact

The determination of hemoglobin mass might possibly be used as a clinical diagnostic parameter and facilitate the differentiation between true anemia and hemodilution in heart failure patients. The identification of exercise-related changes in hemoglobin mass and blood volume could also contribute to individualized treatment strategies. In addition, the project should help to understand the underlying mechanisms of changes in hemoglobin mass and blood volume induced by physical exercise.

References